IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* AMY BERGMAN; THE DISTRICT OF COLUMBIA *ex rel.* AMY BERGMAN, CALIFORNIA *ex rel.* AMY BERGMAN, DELAWARE *ex rel.* AMY BERGMAN, FLORIDA *ex rel.* AMY BERGMAN, GEORGIA *ex rel.* AMY BERGMAN, HAWAII *ex rel.* AMY BERGMAN, ILLINOIS *ex rel.* AMY BERGMAN, INDIANA *ex rel.* AMY BERGMAN, LOUISIANA *ex rel.* AMY BERGMAN, MASSACHUSETTS *ex rel.* AMY BERGMAN, MICHIGAN *ex rel.* AMY BERGMAN, MONTANA *ex rel.* AMY BERGMAN, NEVADA *ex rel.* AMY BERGMAN, NEW HAMPSHIRE *ex rel.* AMY BERGMAN, NEW JERSEY *ex rel.* AMY BERGMAN, NEW MEXICO *ex rel.* AMY BERGMAN, NEW YORK *ex rel.* AMY BERGMAN, OKLAHOMA *ex rel.* AMY BERGMAN, RHODE ISLAND *ex rel.* AMY BERGMAN, TENNESSEE *ex rel.* AMY BERGMAN, TEXAS *ex rel.* AMY BERGMAN, VIRGINIA *ex rel.* AMY BERGMAN, WISCONSIN *ex rel.* AMY BERGMAN, and AMY BERGMAN individually , Plaintiffs, v. ABBOTT LABORATORIES, Defendant.	Civil Action No. 09-4264 (CDJ)

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT'S MOTION TO DISMISS

Marc J. Sonnenfeld
John C. Dodds
Dirkje Camille Frey
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5000

Mark Filip*
Henry J. DePippo*
Elizabeth S. Hess*
KIRKLAND & ELLIS LLP
300 N. LaSalle
Chicago, IL 60654
Telephone: (312) 862-2000

Counsel for Defendant
Abbott Laboratories
**admitted pro hac vice*

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INTRODUCTION

Amy Bergman brings this action against Abbott, asserting theories of liability under the False Claims Act predicated on purported "off-label" marketing of Abbott's successful lipid-regulating pharmaceutical, TriCor. Tellingly, neither the United States, nor any of the individual states that Bergman purportedly represents, has intervened in this action. The problems with Relator's complaint are legion and begin, most basically, with the failure to plausibly allege any "off-label" marketing at all. Indeed, Bergman's conclusory assertions of alleged "off-label" uses encouraged by Abbott are belied by the FDA-approved label itself which expressly encompassed those uses during the time-period in question. But even if Bergman's Complaint were sufficient to allege "off-label" marketing, that is not enough to state a claim under the False Claims Act or any of the state-law theories she pursues. Indeed, the False Claims Act is not a vehicle through which any would-be plaintiff can assert violations of the Food, Drug, and Cosmetic Act or Food and Drug Administration regulations, and courts have repeatedly rejected attempts to bootstrap such contentions into a False Claims Act claim where there are not sufficient allegations of *false claims for payment* made to the government. The law is clear that Relator must allege facts sufficient to show that a violation was a *precondition* for payment of claims. Here, she does not and cannot. It is undisputed that the purportedly "off-label" uses are medically accepted uses—identified as such in the compendia listed by federal law—and therefore are properly compensable under federal and state law. Even more fundamentally, however, Relator fails to allege *with particularity* any facts surrounding the submission of a single false claim for payment. Federal Rule of Civil Procedure Rule 9(b) stands as a bulwark against vague and conclusory assertions of fraud such as those that permeate the Complaint. In the end, Relator is left with nothing more than bald assertions that are insufficient to state a claim under the False

Claims Act as a matter of law, much less in accordance with Rule 9(b), and the Amended Complaint should be dismissed.

BACKGROUND

A. The Food, Drug, and Cosmetic Act

The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, empowers the Food and Drug Administration ("FDA") to regulate the marketing and promotion of prescription drugs, such as TriCor. The FDCA provides the FDA with exclusive federal regulatory authority over the approval of new prescription drugs and prescription drug marketing.

The FDCA precludes the FDA, however, from interfering with the medical judgment and prescribing decisions of healthcare practitioners. The FDCA was not intended to—and does not—regulate the practice of medicine. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001) (describing "the FDA's mission to regulate in th[e] area [of medical devices] without directly interfering with the practice of medicine[]" and citing sources); *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012) (explaining that "the FDCA does not regulate the practice of medicine" in the context of physicians' prescription of drugs and citing sources); *see also* Am. Compl. ¶ 41 (Dkt. 18).

Thus, although the FDA's authority allows it to prohibit drug companies from promoting off-label uses of drugs, it cannot prohibit physicians from prescribing drugs for such uses: "Because the FDCA does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses." *In re Schering Plough*, 678 F.3d at 240; *cf. Buckman*, 531 U.S. at 350 ("'[O]ff-label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."). In other words, "[a] physician may prescribe a legal drug to serve any purpose that

he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA." *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000). The FDCA also does not create a private cause of action for off-label marketing, *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 241 (3d Cir. 1990), and state causes of action for alleged violations of the FDCA are preempted. *See Buckman*, 531 U.S. at 348, 350.

B. Provisions Governing Medicare Reimbursement

Just as the FDCA regulates the promotion of prescription drugs without granting the FDA authority to interfere with medical practitioners' prescribing decisions, Medicare—a federally funded health insurance program for the elderly and disabled administered by the Centers for Medicare & Medicaid Services ("CMS")—does not authorize the federal government, when it makes reimbursement determinations, to exercise "control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. § 1395. Instead, Medicare reimbursement hinges upon whether a product or service is deemed "reasonable and necessary for the diagnosis or treatment" of an illness. *Id.* § 1395y(a)(1)(A). CMS has interpreted "reasonable and necessary" to include any treatment that is appropriate, meaning the treatment is "[f]urnished in accordance with acceptable standards of medical practice for the diagnosis or treatment of the patient's condition." (*See* Ex. 1, Medicare Program Integrity Manual § 13.5.1.)

Similarly, the Medicaid statute defines "covered outpatient drug" as not including "a drug or biological used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). The statute defines "medically accepted indication" to include not only a use approved by the FDA under the FDCA, but also a use which is supported by one or more citations in a medical compendium. 42 U.S.C. § 1396r-8(k)(6) (enumerating qualifying compendia). Thus, it is not uncommon for a drug to be prescribed for an "off-label" use not

approved by the FDA that still qualifies as a "medically accepted indication" eligible for federal reimbursement under Medicaid.

C. The Amended Complaint

TriCor is a lipid-regulating agent approved by the FDA for the treatment of hypercholesterolemia, mixed dyslipidemia, and hypertriglyceridemia. (Am. Compl. ¶ 4.) Relator alleges that Abbott engaged in a nationwide scheme to market the drug TriCor for uses other than its FDA-approved indications. (*Id.* ¶¶ 5-6.) This off-label marketing allegedly resulted in the submission of claims for purportedly off-label uses to the federal government and the States, giving rise to liability under the False Claims Act. (*Id.* ¶ 11.)

Relator's Amended Complaint ("Complaint") describes two types of alleged off-label marketing and promotion by Abbott: (1) for the use of TriCor as a "first-line treatment" for diabetes; and (2) for the use of TriCor in combination with statin drugs. (*Id.* ¶ 7.) According to Relator, the "[p]rescriptions for TriCor which resulted from Abbott's illicit off-label marketing . . . were not for medically accepted indications and therefore were not eligible for reimbursement under Medicaid, Medicare or other federal health care programs." (*Id.* ¶ 131.)

Under a different theory of False Claims Act liability, Relator alleges that, as part of its marketing scheme for TriCor, Abbott allegedly made "illegal kickbacks and prohibited remuneration to physicians in order to induce them to prescribe TriCor for Medicare, Medicaid and other Government health insurance programs' covered patients." (*Id.* ¶ 120.)

LEGAL STANDARDS

Under Federal Rule of Civil Procedure 12(b)(6), the Court must dismiss a claim if Relator fails to allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). It is not enough to plead facts that "permit

the court to infer . . . the mere *possibility* of misconduct." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) (emphasis added). Rather, the Complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555; *see also McTernan v. City of York*, 577 F.3d 521, 530 (3d Cir. 2009); *Umland v. Planco Fin. Servs., Inc.*, 542 F.3d 59, 64 (3d Cir. 2008). Importantly, "[w]here a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Iqbal*, 556 U.S. at 679 (quoting *Twombly*, 550 U.S. at 557). Moreover, the Court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Metro Commercial Real Estate Inc. v. CIBC Inc.*, No. 11–7480, 2012 WL 5287905, at *2 (E.D. Pa. Oct. 25, 2012) (quoting *Papasan v. Allain,* 478 U.S. 265, 286 (1986)).

On a motion to dismiss, the Court must consider the "complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010); *see also Metro Commercial* 2012 WL 5287905, at *2. Accordingly, the Court may consider documents such as medical compendia on which government healthcare programs rely to determine whether to reimburse for a drug. *See, e.g.*, *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007) (considering documents from one of the compendia on which Medicaid programs rely to determine whether to reimburse for a drug); *see also* 42 U.S.C. § 1396r-8(k)(6); 42 U.S.C. § 1396r-8(g)(1)(B)(i) . Thus, "exhibits attached to the complaint and facts of which the court will take judicial notice" may be considered without converting a motion to dismiss into a motion for summary judgment. *Pryor v. Nat'l Coll. Athletic Ass'n,* 288 F.3d

548, 560 (3d Cir. 2002); 5B Wright & Miller, *Federal Practice & Procedure* § 1357 (3d ed. 2004).[1]

SUMMARY OF ARGUMENT

The False Claims Act ("FCA") prohibits knowingly submitting, or causing to be submitted, a false or fraudulent claim for payment to the government, 31 U.S.C. § 3729(a)(1)(A), as well as knowingly creating, or causing to be created, a false record to be used in support of such a claim, 31 U.S.C. § 3729(a)(1)(B). In order to establish a prima facie FCA violation, Relator "must prove that '(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.'" *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 304-05 (3d Cir. 2011) (quoting *United States ex rel. Schmidt v. Zimmer, Inc.* ("*Zimmer* I"), 386 F.3d 235, 242 (3d Cir. 2004)). Relator cannot make that showing here because, despite its length, the Complaint does not allege facts which, even if accepted as true, support a conclusion that any claims were submitted to the government, or that any claims were false, let alone that such claims were caused by Abbott's conduct, knowingly or otherwise.

Relator alleges that Abbott made various misrepresentations related to the safety and efficacy of TriCor and engaged in marketing practices that, she asserts, violated the FDCA. But the FDCA provides no private right of action and the FCA "was not designed for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment." *Wilkins*, 659 F.3d at 307 (quoting *Mikes v. Straus*, 274 F.3d

[1] The Court, therefore, may properly consider the matters outside the pleadings presented with this motion for the purpose for which they are offered without converting the motion into a motion for summary judgment.

687, 699 (2d Cir. 2001)); *Rodriguez v. Our Lady of Lourdes Med. Ctr.*, 552 F.3d 297, 304 (3d Cir. 2008) ("[I]t is necessary to allege not only a receipt of federal funds and a failure to comply with applicable regulations, but also that payment of the federal funds was in some way conditioned on compliance with those regulations."). Accordingly, "[t]he [FCA] does not create a cause of action against all fraudulent conduct affecting the government. . . . FCA liability does not attach to violations of federal law or regulations, such as marketing of drugs in violation of the FDCA, that are independent of any false claim." *Rost*, 507 F.3d at 727. Here, Relator's allegations do not state a claim under the FCA because the alleged conduct, even if true, did not result in the submission of false claims for payment to the government.

Relator contends Abbott marketed TriCor for "off-label" uses. This theory of FCA liability depends on several stark assumptions unsupported by any plausibly alleged facts: that such marketing must have led doctors to prescribe TriCor for such uses, that pharmacists must have submitted claims for reimbursement for those prescriptions to government healthcare programs, and that those claims for reimbursement must have been false or fraudulent because off-label prescriptions are always ineligible for reimbursement. Each prong of Relator's theory is fatally flawed. First, the uses she describes in her Complaint were not "off-label" because those uses fall within the FDA-approved indications for TriCor. Second, even off-label prescriptions may be eligible for reimbursement and therefore are not necessarily false claims; indeed, it is not the FDA-approved indication, but rather the broader universe of medically acceptable uses that determines whether a claim is reimbursable. Relator's conclusory assertions that claims were for "medically unnecessary" uses are supported with no factual allegations whatsoever, and fall far short of Fed. R. Civ. Proc. 12(b)(6)'s pleading requirements as described in *Twombly* and *Iqbal*, to say nothing of the more stringent standard of Rule 9(b). Further, if

anything, such assertions are legal, not factual, and are incorrect as a matter of law. Finally, the Complaint fails to allege a sufficient causal link between Abbott's conduct and the filing of the alleged false claims to satisfy the pleading requirements of Rule 9(b).

In addition to these reasons, Relator's Complaint also fails to adequately plead with respect to violations of the Anti-Kickback Statute ("AKS")—which Relator uses to supplement her primary theory of FCA liability—because the Complaint does not allege the "who, what, when, where and how" of both the alleged AKS violations and the resulting false claims, as required by Rule 9(b). Relator's claims are also subject to a six-year statute of limitations, which requires that Counts I and II be dismissed to the extent they relate to alleged false claims submitted prior to September 18, 2003. Finally, the claims alleged by Relator under the false claims acts of twenty-two states and the District of Columbia should be dismissed because they are barred for various reasons including her failure to properly plead the claims with particularity, the failure of certain states to intervene as required by statute, improper retroactive application of state law, the applicable statutes of limitations, and other reasons set forth in detail below.

I. AS THE LABEL ITSELF DEMONSTRATES, THE CLASS OF PRESCRIPTIONS IDENTIFIED BY THE COMPLAINT WERE NOT OFF-LABEL USES.

Relator alleges that Abbott caused false claims for reimbursement to be submitted to government healthcare programs because the claims sought reimbursement for off-label prescriptions of TriCor. (Am. Compl. ¶ 11.) Relator's claims are predicated on two allegedly off-label uses: (1) the use of TriCor "as a first-line treatment of diabetic patients," Am. Compl. ¶ 65, and (2) the use of TriCor "in combination therapy with statins." (*Id.* ¶ 84.) These claims fail because any prescriptions allegedly written by doctors for such uses were not off-label, and

any resulting claims for reimbursement were not false or fraudulent, even under Relator's erroneous legal theory that claims for off-label prescriptions are necessarily "false."

A. The Use of TriCor to Treat Dyslipidemia in Patients with Diabetes Fell Within TriCor's Approved Indications.

Relator acknowledges, as she must, that throughout the relevant time period, TriCor was FDA-approved as a "lipid regulating agent" and was indicated for the treatment of hypercholesterolemia, mixed dyslipidemia, and hypertriglyceridemia. (*Id.* ¶¶ 56-57.) Although Relator baldly claims that Abbott marketed TriCor as a "first-line drug for treatment of diabetic patients despite the lack of an FDA approved indication for such use," *id.* ¶ 65, her own allegations demonstrate that Abbott simply highlighted the benefits of TriCor as a *lipid regulating agent* for use by diabetic patients with mixed dyslipidemia, a condition characterized by a combination of high LDL cholesterol and high triglyceride levels, *id.* ¶¶ 63, 69. Diabetic patients are at a special risk of dyslipidemia and are therefore more likely to require a lipid regulating agent, such as TriCor, to treat the condition.[2] That is why, as noted in the Complaint, the American Diabetes Association recommended that diabetics be prescribed lipid-lowering drugs. (*Id.* ¶ 63.)

Although Relator suggests that the treatment of diabetic patients with TriCor is an off-label use, nowhere does her Complaint allege any facts—as opposed to bald legal conclusions—indicating that Abbott marketed the product as anything other than a lipid-regulating agent approved for the treatment of mixed dyslipidemia, hypertriglyceridemia, or

[2] The American Diabetes Association Standards of Care explicitly recognize that "[l]ow levels of HDL cholesterol, often associated with elevated triglyceride levels, are the most prevalent pattern of dyslipidemia in persons with type 2 diabetes." (*See* Ex. 2, *Standards of Medical Care in Diabetes-2012*, Diabetes Care, Vol. 35, Supp. 1, January 2012, at S31.)

hypercholesterolemia, conditions that happen to be common among the diabetic population. (*Id.* ¶¶ 56-57, 66-69 and Am. Compl. Ex. 3 at 5.) *See also* 42 U.S.C. § 1395x(yy)(2). Relator's own exhibits show that Abbott simply regarded a "[d]iabetic patient ***with mixed dyslipidemia***[]" as a relevant "patient type" for TriCor. (Am. Compl. Ex. 2 at 1 (emphasis added); *see id.* at 3 (noting that "many . . . patients with diabetes also have mixed dyslipidemia").) Indeed, TriCor was indicated for the treatment of mixed dyslipidemia and was not contraindicated for patients with diabetes. Accordingly, as reflected in the very materials Relator relies upon in her Complaint, the promotion of TriCor as a treatment for mixed dyslipidemia, in patients with or without diabetes, was for an FDA-approved indication, not an off-label use.

Relator also alleges that, in the course of promoting TriCor for the treatment of mixed dyslipidemia among diabetics, Abbott misrepresented the safety and efficacy of the drug to doctors. (Am. Compl. ¶ 70.) Even if accepted as true, these allegations are not relevant to a claim under the FCA because, as discussed in greater detail below, regulatory violations that do not violate a precondition for payment of claims do not provide a basis for FCA liability. *See Wilkins*, 659 F.3d at 309 ("[T]o plead a claim upon which relief could be granted . . . a plaintiff must show that compliance with the regulation which the defendant allegedly violated was a condition of payment from the Government."). Again, the FCA is not a cure-all for purported violations of the FDCA; rather, Congress has vested the FDA with exclusive authority to enforce the FDCA. If the ultimate prescription for TriCor was within a medically accepted indication, then there could be no false claim for reimbursement based on that prescription, regardless of any alleged misrepresentation by Abbott. *See Wilkins*, 659 at 307, 309. It is nonetheless worth noting that Relator's conclusory allegations of misrepresentation cannot withstand scrutiny under Rule 12(b)(6). For example, Relator alleges that Abbott offered the "false and misleading

assertion that TriCor was a stronger fibrate drug than gemfibrizol [*sic*]." (Am. Compl. ¶ 73.) That assertion, however, is supported by a recognized compendium, the American Hospital Formulary Service Drug Information, which reported during the relevant period that "[w]hile few studies are available on the comparative efficacy of fenofibrate and other antilipemic agents, limited data suggest that fenofibrate may have more favorable effects on serum total cholesterol and LDL-cholesterol concentrations than gemfibrozil."[3] Relator also makes allegations about various studies that she claims have demonstrated that TriCor is not an effective treatment for diabetics with mixed dyslipidemia. But the very article she cites in her Complaint for the "questionable use of TriCor" indicates that doctors viewed TriCor as an appropriate treatment for diabetic patients with elevated triglyceride levels—even in combination with statins.[4] Thus, even if Relator's allegations were correct, and not inconsistent with the very documents she cites, it would make no difference because the alleged prescriptions were on-label and indisputably medically accepted.

Because Relator specifically alleges only on-label marketing of TriCor to patients who also have diabetes, she has failed to state a claim under the FCA.

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[3] Ex. 3, Fenofibrate (TriCor), American Hospital Formulary Service Drug Information, at 1714 (2008). The Medicaid statute incorporates the American Hospital Formulary Service Drug Information and other medical compendia into the definition of "medically accepted indication." 42 U.S.C. § 1396r-8(k)(6). By definition, a drug prescribed for a use supported by a citation in one of the enumerated compendia is for a medically accepted indication and therefore eligible for federal reimbursement.

[4] Ex. 4, Jane E. Allen, *Doctors Push Fibrate Cholesterol Drugs Despite Scant Evidence of Effectiveness*, abcews.com (March 23, 2011), *available at* http://abcnews.go.com/Health/HeartDiseaseTreatment/rise-fibrate-cholesterol-drug-prescriptions-questioned/story?id=13196655 ("[F]or a subgroup of diabetics whose cholesterol is well-controlled by statins, but whose triglycerides remain elevated, ACCORD provided what [the lead investigator for the study] called 'good evidence' that they could benefit by adding fenofibrate.") (cited at Am. Compl. ¶ 108). Note that the study results supported the prescription of TriCor not only for diabetics but also in combination with statins.

B. The Use of TriCor as an Add-On Therapy in Patients Already Taking Statins Is a Use Specifically Contemplated by the FDA.

Relator also alleges that Abbott encouraged doctors to prescribe TriCor instead of a statin drug or, if the doctor was unwilling to replace the statin, to prescribe TriCor in addition to the statin. (Am. Compl. ¶¶ 77, 85.) In other words, Abbott allegedly promoted TriCor as a mono-therapy or an add-on therapy for patients with elevated triglycerides. Yet, even accepting Relator's allegations as true, any prescriptions that allegedly resulted from such promotional efforts were intended to treat hypertriglyceridemia—a condition *not* treated by statins—which is an FDA-approved use for TriCor and thus not an off-label use. (Am. Compl. Ex. 1.) Moreover, contrary to Relator's conclusory assertions, the use of TriCor in combination with statin drugs is a use specifically contemplated by TriCor's FDA-approved labeling provided that the prescribing physician believes that "the benefit of further alterations in lipid levels is likely to outweigh the increased risk" of the use of TriCor in combination with statins. (*Id.*)

Relator alleges that Abbott advocated the use of TriCor not only as a replacement for statins, but also as an add-on therapy where the doctor would not replace the statin prescription. (Am. Compl. ¶¶ 84-85.) Even if true, Relator's allegations amount to an assertion that Abbott was promoting TriCor as having a benefit for patients with high triglycerides that is not provided by a statin. As noted above, the combined use of TriCor with statin drugs is not an "off-label" use because the FDA-approved label specifically recognized that TriCor may be prescribed for combination use provided that the prescribing physician determined that the benefits of such combination use outweighed the potential risks. (Am. Compl. Ex. 1.) Nowhere does Relator allege that Abbott promoted TriCor contrary to its labeling by encouraging doctors to use the drug in combination where the benefits did *not* outweigh any potential risks. Therefore, even

accepting Relator's allegations as true, those allegations are insufficient to support a claim of off-label promotion of TriCor for combination use. Relator's allegations, thus, cannot state a claim under the FCA.

II. RELATOR'S ALLEGATIONS ARE NOT SUFFICIENT TO STATE A CLAIM UNDER THE FALSE CLAIMS ACT BECAUSE THEY DO NOT SHOW THAT ANY CLAIMS SUBMITTED FOR REIMBURSEMENT WERE FALSE OR FRAUDULENT.

Even if the use of TriCor by diabetic patients or in combination with statins were off-label uses, Relator still would not be able to state a claim under the FCA. The FCA does not authorize Relator to stand in the shoes of the FDA to enforce compliance with federal drug marketing regulations. *See Wilkins*, 659 F.3d at 310 ("[W]e question the wisdom of regarding every violation of a Medicare regulation as a basis for a *qui tam* suit. Federal agencies are unquestionably better suited than federal courts to ensure compliance with Medicare marketing regulations.") (internal citations omitted). Relator can only maintain a case under the FCA by alleging *fraudulent conduct* that relates to a necessary *precondition for payment* of claims, *i.e.*, that claims for off-label prescriptions were "false claims" under the FCA because compliance with the FDA regulations at issue was a precondition for reimbursement.

In *Wilkins*, the Third Circuit made clear that the alleged failure to comply with a regulation unrelated to a condition for receipt of payment from the government does not give rise to a claim under the FCA. *Id.* at 309-10. In *Wilkins*, the relators alleged that United Health Group violated federal regulations governing the promotion of Medicare supplemental insurance plans both by using unapproved marketing techniques and by providing improper remuneration to healthcare providers in order to induce them to place patients on United Healthcare's plans. *Id*. at 300. The *Wilkins* court held that the relators failed to state a claim under the FCA because,

while compliance with the Medicare marketing regulations at issue was a condition for eligibility to participate in Medicare programs, it was not a precondition for payment of claims. *Id*. at 309. According to the *Wilkins* court, "the fundamental flaw in appellants' allegations is that the amended complaint does not cite to any regulation demonstrating that a participant's compliance with Medicare marketing regulations is a condition for its receipt of payment from the Government." *Id*. at 309-10.

As with the complaint in *Wilkins*, Relator's Complaint here is fatally flawed because Relator does not—and cannot—point to any authority demonstrating that compliance with the FDCA, which governs the marketing and promotion of prescription drugs, is a condition for payment for those drugs under Medicare and related government healthcare programs. Relator's claims that Abbott engaged in off-label marketing of TriCor for purposes other than those approved by the FDA are no more than conclusory allegations that Abbott violated marketing or labeling regulations. But the touchstone of Medicare and Medicaid reimbursement is not compliance with FDA marketing regulations or labeling. Rather, the relevant standard is the much broader category of "medically accepted" indications and reimbursement extends to prescriptions that are "medically necessary." Compliance with these standards—***not*** the FDA-approved label or laws and regulations governing the marketing and promotion of prescription drugs—is the relevant precondition for payment under Medicare and Medicaid.

During the relevant period of time, however, it is indisputable that the alleged uses of TriCor—by diabetic patients with lipid disorders or as an add-on therapy in patients already taking statins—were supported, as a matter of law, by citations in medical compendia and therefore fell within the medically accepted indication for TriCor. 42 U.S.C. § 1396r-8(k)(6).

Relator fails to allege a single fact supporting her conclusory allegations to the contrary and, therefore, has not plausibly alleged any false or fraudulent claims for payment.

A. Prescriptions for Medically Accepted Off-Label Uses are Reimbursable Under Medicare and Related Federal Healthcare Programs.

Even if the prescriptions that the Complaint alleges were written for TriCor were considered "off-label," and even if reimbursement requests for such prescriptions were eventually filed with government healthcare programs, those reimbursement requests would not be false claims because even off-label prescriptions are eligible for reimbursement. *See* 42 U.S.C. §§ 1395x(t)(2), 1395y(a)(1)(A). The touchstone for reimbursement under Medicare is whether the prescription is for a "medically accepted indication," 42 U.S.C. § 1395y(a)(1)(A), which includes not only the FDA-approved indications listed on the label but also uses that are supported by one or more citations in a medical compendium. 42 U.S.C. § 1396r-8(k)(6).

Relator recognizes as much with respect to some of the healthcare programs at issue. She acknowledges, for example, that the TRICARE program will cover prescriptions made for an off-label use if "such off-label use is proven medically necessary and safe and effective in medical literature, national organizations, or technology assessment bodies." (Am. Compl. ¶ 151.) Relator also recognizes with respect to the Federal Employees Health Benefits Program that "the benefit plans for the major FEHBP insurance carriers" provides that there is no coverage for drugs "that are not medically necessary." (Am. Compl. ¶ 158.)[5] Therefore,

[5] *See* Ex. 5, Andy Schneider, *Tennessee's New "Medically Necessary" Standard: Uncovering the Insured?*, Kaiser Commission Policy Brief, July 2004, *available at* http://www.kff.org/medicaid/loader.cfm?url=/commonspot/security/ getfile.cfm&pageid= 44707 (noting that FEHBP does not have a definition of "medically necessary" and individual plans use their own definitions); Ex. 6, BlueCross and BlueShield Service Benefit Plan 2012 at 130-31, *available at* http://www.opm.gov/insure/health/planinfo/2012/brochures/71-005.pdf; Ex. 7, 2012 APWU Health Plan at 111-12, *available at*

prescriptions for medically necessary uses for TriCor are eligible for reimbursement, and as explained below, TriCor prescriptions were "medically necessary" within the meaning of 42 U.S.C. § 1396r-8.

B. The TriCor Prescriptions Alleged in the Complaint Meet the Definition of Medical Necessity and Are Therefore Reimbursable Under Medicare and Related Federal Healthcare Programs.

Relator has failed to plead any facts supporting her bald assertion that claims arising from the use of TriCor by diabetic patients with lipid disorders or by patients in combination with statins were "medically unnecessary." *See, e.g., Iqbal*, 556 U.S. at 678 (mere "legal conclusions," "[t]hreadbare recitals of the elements of a cause of action," or "conclusory statements" are insufficient to state a claim under Rule 12(b)(6), let alone the more stringent standard of Rule 9(b)). This is because there are no facts to support her allegations. The use of TriCor as an add-on therapy in patients already taking statins and as a lipid-regulating agent for diabetic populations, as alleged by Relator in her Complaint, were both indisputably medically accepted indications within the meaning of the statute.

Regarding combination therapy, the health benefit of lowering triglycerides and raising HDL cholesterol provided by a fenofibrate such as TriCor—not realized by taking a statin alone—is supported by the American Hospital Formulary Service Drug Information: "Fenofibrate appears to be more effective than hydroxymethylglutaryl coenzyme A (HMG-CoA)

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http://www.opm.gov/insure/health/planinfo/2012/brochures/71-004.pdf at 111-12; Ex. 8, 2012 MHBP at 93, *available at* http://www.opm.gov/insure/health/planinfo/2012/brochures/71-007.pdf; *see also* Ex. 9, FEHBP website, http://www.opm.gov/insure/health/planinfo/index.asp (listing all FEHBP plans by state). Private insurers also employ a definition of medical necessity which includes health care services that are appropriate for the diagnosis or treatment of a condition, illness, or injury; are not cosmetic or primarily for convenience; and are not unreasonably costly. *See, e.g.*, Ex. 10, Medical Necessity Definitions, http://www.cigna.com/customer_care/healthcare_professional/medical/medical_necessity_definitions.html.

reductase inhibitors (statins) in lowering triglyceride and increasing HDL-cholesterol concentrations but generally is less effective in reducing LDL-cholesterol concentrations."[6] This use of TriCor is therefore, by definition, a "medically accepted indication," 42 U.S.C. § 1396r-8(k)(6) (defining "medically accepted indication" to include a use "supported by one or more citations included or approved for inclusion in any of the compendia described in 42 U.S.C. § 1396r-8(g)(1)(B)(i)"). A drug prescribed for that indication would be a "covered outpatient drug" eligible for federal reimbursement, so any resulting claims for reimbursement would not be false claims as a matter of law.

Indeed, the use of fibrates as an adjunctive therapy with statins was so well-accepted that the National Institutes of Health have recommended such combination therapy for over a decade. The Third Report of the National Cholesterol Education Program on the Treatment of Cholesterol in Adults, published by the National Institutes of Health in September 2002, explained that "[t]he combination of statins and fibrates has proven to be highly effective for improvement of the lipoprotein profile in patients with combined hyperlipidemia. It also may be useful for patients with elevated LDL cholesterol and atherogenic dyslipidemia."[7] The same publication also explained that "[i]n the past, this combination was widely thought to be 'contraindicated' because of the potential danger of myopathy. More recently, statin-fibrate

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[6] Ex. 3, Fenofibrate (TriCor), *American Hospital Formulary Service Drug Information*, at 1714 (2008).

[7] Ex. 11, National Institutes of Health, *Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report*, at VI-20 (2002), *available at* http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf; *see also* Ex. 12, Jody Lounsbery, et al., *Add a Fibrate to a Statin?*, 59 J. Family Prac. 582 (2010), *available at* http://www.jfponline.com/Pages.asp?AID=9003 (noting that the National Cholesterol Education Program Adult Treatment Panel III guidelines "recommend combination fibrate-statin therapy for all patients when statin therapy alone is not adequate to achieve lipid goals").

combination therapy has been used with apparent safety in the majority of persons."[8] This and other authorities established that the use of TriCor in diabetics and concurrently with statins was medically appropriate. Thus, Relator's conclusory assertion suggests that the use of TriCor as an add-on therapy for patients taking statins was not "proven medically necessary and safe and effective in medical literature, national organizations, or technology assessment bodies," Am. Compl. ¶ 151, is belied by the very compendia that the statute identifies as "medically accepted indication."[9] Again, the question for this is not whether the prescriptions were "medically necessary" and safe in the abstract, but whether it was a "covered outpatient drug" within the meaning of the statute. The compendia demonstrates conclusively as a matter of law, it was.

The same is true regarding the use of TriCor by diabetic patients. A recognized compendium entry for TriCor's drug class (fenofibrates) specifically describes evidence that the use of fenofibrates "in patient with type 2 diabetes mellitus . . . may slow the progression of coronary atherosclerosis."[10] Even more significantly, the "General Principles of Antilipemic

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[8] *Id.*

[9] Relator further alleges that Abbott "fail[ed] to present a balanced presentation regarding the benefits and risks of TriCor," Am. Compl. ¶ 151, and "minimize[ed] the risks of such use, as well as the critical importance of weighing the benefit against the increased risk of combination therapy, as described in the package insert, and as required by the FDA and the FDCA," *id.* ¶ 90. But those allegations, even if true, do not state a claim under the FCA. Relator has not demonstrated—and cannot demonstrate—that this conduct violated a precondition for reimbursement (likely for the plain reason that such a position would be unsupported by law). *See Wilkins*, 659 F.3d at 307 (quoting *Mikes*, 274 F.3d at 699). Moreover, allegedly misrepresenting the safety of a drug does not violate the FCA if the misrepresentation did not knowingly cause the submission of a false claim for payment to the government. *See id.*, 659 F.3d at 309-10. Finally, regardless of these allegations, a prescription for TriCor intended to reduce triglycerides or lipids in the patient is not for an off-label use—it is both on-label and for a medically accepted use—and therefore a claim for reimbursement based on such a prescription is not a false claim for payment; neither allegation overcomes this fundamental defect in Relator's theory of liability.

[10] Ex. 3, Fenofibrate (TriCor), American Hospital Formulary Service Drug Information, at 1714, 1716 (2008).

Therapy in the HMG-CoA Reductase Inhibitors General Statement," explicitly incorporated into the compendium entry for TriCor, extensively catalogs the importance of using fenofibrates in the treatment and regulation of diabetes.[11] These treatment approaches were recognized and encouraged in medical literature and by the American Diabetes Association.[12]

Relator has therefore not sufficiently alleged, and cannot allege, that prescriptions for TriCor to the classes of patients identified in her Complaint—diabetic patients with lipid irregularities and those receiving statin therapy—were not medically necessary. *See United States ex rel. Bennett v. Boston Scientific Corp.*, No. H-07-2467, 2011 WL 1231577, at *27 (S.D. Tex. Mar. 31, 2011) (dismissing complaint because "[t]he authorities cited by the relator do not provide a basis to infer that a reimbursement submission for [a particular treatment] cannot be medically necessary . . . because it is not specifically approved for that purpose[]"); *United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 347-48 (D. Mass. 2011) ("Thus, to the extent that [Relator's] claim alleges that the claims for off-label use are 'categorically' false because the device is unapproved for that use . . . she fails adequately to state a claim for relief in accordance with Rule 12(b)(6).").

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[11] *See* Ex. 13, *HMG-CoA Reductase Inhibitors General Statement*, American Hospital Formulary Service Drug Information 2008, at 1721, 1722 (identifying diabetes mellitus as a risk factor recommending for LDL-cholesterol regulation in children and adolescents including through the use of antilipemic therapy); *id.* at 1724 (recommending use of fibric acid derivatives in patients with diabetes mellitus particularly where statin therapy has failed to achieve needed dyslipidemia profile).

[12] *See, e.g.*, Ex. 14, *Dyslipidemia Management in Adults With Diabetes*, Diabetes Care, Vol. 27, Supp. 1, January 2004, *available at*: http://care.diabetesjournals.org/content/27/suppl_1/s68.full (describing and recommending use of fibric acid derivatives (fenofibrates) in management of lipid-regulation issues for adult diabetic populations both alone and in combination with other drug classes such as statins).

C. State Medicaid Programs Also Reimburse for Non-FDA Approved Uses of Prescription Drugs.

Relator alleges with respect to Medicaid—as opposed to Medicare—that "[t]he States statutorily limit, with narrow exceptions not applicable here, Medicaid reimbursement for prescription drugs to those uses approved by the FDA." (Am. Compl. ¶ 146.) This allegation is not only improperly conclusory, it is also wrong as a matter of law.

First, Medicaid plainly covers non-approved uses that are supported by a citation in a medical compendium, such as those discussed above. *See* 42 U.S.C. § 1396r-8(k)(6); *see also Bennett*, 2011 WL 1231577, at *5 n.5; *United States ex rel. Marchese v. Cell Therapeutics, Inc.*, No. CV06-0168MJP, 2007 WL 4410255, at *1 (W.D. Wash. Dec. 14, 2007); *United States ex rel. Banignan v. Organon USA Inc.*, No. 07-12153-RWZ, 2012 WL 1997874, at *12-13 (D. Mass. June 1, 2012).

Second, states may and do cover off-label prescriptions. *See, e.g.*, Mass. Regs. Code tit. 130, § 406.413(C)(4) ("The MassHealth agency does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert, except as the MassHealth agency determines to be consistent with current medical evidence."); Ex. 15, Michigan Medicaid Provider Manual, § 6 at 12 (listing as non-covered "[d]rugs prescribed for 'off label' use if there is no generally accepted medical indication in peer reviewed medical literature (Index Medicus), or listing of such use in standard pharmaceutical references such as Drug Facts and Comparisons, AMA Drug Evaluations, American Hospital Formulary Service Drug Information, or DRUGDEX Information Systems"), *available at* http://www.michigan.gov/mdch/0,1607,7-132--87572--,00.html; N.H. Code Admin. R. HE-W § 570.04(a) (reimbursing medications for a "use specified by the FDA, or for non-experimental purposes, as supported by accepted medical

practice"); 89 Ill. Admin. Code §§ 140.414(a) (noting prescriber "may prescribe any pharmacy item, not otherwise excluded, that, in the prescriber's professional judgment, is essential for the diagnosis or accepted treatment of a recipient's present symptoms"), 140.441 (off-label prescriptions not among categories of pharmaceutical "services not covered"), 140.442(b) (noting prior approval should be given for drug used in accordance with standards listed in compendia).[13]

Moreover, as one court recently observed, "if a state Medicaid program chooses to reimburse a claim for a drug prescribed for off-label use, then that claim is not 'false or fraudulent,' and liability cannot therefore attach for reimbursement." *Organon USA*, 2012 WL 1997874, at *12. The Medicaid statute "appears to give states the ability to choose whether they will cover off-label, non-compendium prescriptions." *Id.*; *see* 42 U.S.C. § 1396r-8(d)(1)(B)(i) ("A State *may* exclude or otherwise restrict coverage of a covered outpatient drug if—(i) the prescribed use is not for a medically accepted indication . . . .") (emphasis added). The permissive language of the statute implies that states are not required to exclude coverage of drugs that are prescribed for off-label uses—even where those drugs lack compendia citations.

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[13] *See also* Ex. 16, Douglass L. Leslie, Ph.D. and Robert Rosenheck, M.D., *Off-Label Use of Antipsychotic Medications in Medicaid*, 18 Am. J, Managed Care e109 (2012), *available at* http://www.ajmc.com/articles/Off-Label-Use-of-Antipsychotic-Medications-in-Medicaid (discussing extensive off-label use of antipsychotic medications in forty-two state Medicaid plans); Ex. 17, Robert J. Buchanan, Ph.D., *Medicaid Managed Care and Coverage of Prescription Medications*, 92 Am. J. Pub. Health 1238, Table 2 (2002) (state-by-state survey of reimbursement for off-label uses by Medicaid managed care organizations); Ex. 18, Defendants' Appendix of State Medicaid Eligibility Guidelines For Reimbursement of Off-Label Uses of Prescribed Drugs (June 3, 2003), *United States ex rel. Franklin v. Parke-Davis*, (D. Mass) (No. 96-11651-PBS), ECF No. 353, *available at* http://dida.library.ucsf.edu/pdf/tpa00a10 (list of state Medicaid eligibility guidelines for reimbursement of off-label uses of drugs); Ex. 5, Andy Schneider, *Tennessee's New "Medically Necessary" Standard: Uncovering the Insured?*, Kaiser Commission Policy Brief, July 2004 (noting considerable variation in how state Medicaid programs define "medically necessary").

Relator's conclusory legal assertion that all the states at issue in this action have chosen not to cover any off-label prescriptions—including those supported in medical compendia—requires a showing that the relevant states have in fact chosen not to do so. *See Organon* USA, 2012 WL 1997874, at *13 (dismissing complaint for failure to show "that any state denies Medicaid coverage for an off-label prescription not included in a medical compendium").

Thus, it is Relator who must plausibly allege specific facts showing that a state does not provide coverage to state a claim. *Organon* provides helpful guidance demonstrating why Relator's allegations are insufficient. In *Organon*, the district court dismissed the complaint based on the coverage discretion possessed by the states under the Medicaid statute because the relators failed to show that the states did not cover off-label, non-compendium prescriptions. *See Organon USA Inc.*, 2012 WL 1997874, at *13 ("Relators do not allege, and Organon does not concede, that any state denies Medicaid coverage for an off-label prescription not included in a medical compendium. Nor do they allege that states must deny coverage of such prescriptions under the Medicaid statute; they allege only that states 'may' do so. This is insufficient to establish that Medicaid reimbursement claims for Remeron filed because of Organon's off-label marketing scheme were 'false or fraudulent.'") (citation omitted). In this case, Relator has failed to make that showing as well. Indeed, many states permit Medicaid reimbursement for off-label uses *regardless* of whether those uses are supported in federally recognized compendia.[14] Apart

[14] *See, e.g.*, Ex. 19, Agency for Health Care Administration, Florida Medicaid Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook, at 2-2 (2012), *available at* https://www.flrules.org/gateway/readRefFile.asp?refId=1261&filename=59G%204250%20Prescribed%20Drugs%20Handbook%20June%202012%20(2).pdf (permitting Medicaid reimbursement in Florida for medically necessary off-label uses based on prior specialist approval); Tit. 130 Mass. Code Regs. § 406.413(C)(4) (permitting Medicaid reimbursement in Massachusetts for non-FDA-approved indications based on agency determination of use "consistent with current medical evidence[]") *and* Ex. 20, MassHealth Drug Utilization Review

from her blanket conclusory allegation, Relator does not allege—because she cannot—that the states actually do deny coverage for the alleged prescriptions at issue here. Relator has therefore failed to state a claim.

The logic of the *Organon* decision applies with even more force to Relator's allegations related to Medicare coverage. The Complaint does not even offer a conclusory allegation that Medicare denies coverage to off-label prescriptions. (*See* Am. Compl. ¶¶ 139-43.) Moreover, for the reasons set forth above, any such allegation would be legally incorrect, as Medicare coverage is based on a "medically necessary" standard, which encompasses a broader range of uses than the FDA-approved labeling. Accordingly, the Complaint fails to allege that the prescriptions were ineligible for reimbursement under Medicare and, therefore, fails to allege

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Program, Lipid Lowering Agent Prior Authorization Request (2012), *available at* https://masshealthdruglist.ehs.state.ma.us/MHDL/pubdownloadpa.do?id=432 (Massachusetts prior authorization request form for, *inter alia*, TriCor with indication check boxes for, *inter alia*, "[s]econdary prevention of cardiovascular event" and "other"); Ex. 15, Michigan Department of Community Health, Medicaid Provider Manual § 6 at 12 (2012), *available at* http://www.mdch.state.mi.us/dch-medicaid/manuals/MedicaidProviderManual.pdf (excluding off-label prescriptions from category of non-covered benefits under Michigan Medicaid program where, among other reasons, prescription has a "generally accepted medical indication in peer reviewed medical literature" or is listed in compendia including non-federally-approved compendia such as Drug Facts and Comparisons); N.H. Code Admin. R. He-W 570.04(a)-(b) (including among list of medications suitable for reimbursement under New Hampshire Medicaid program medications for uses not specified by the FDA where those uses are non-experimental and "supported by accepted medical practice[]"); Ex. 21, Montana Department of Public Health & Human Services, Prescription Drug Program at 2.2 (2011), *available at* http://medicaidprovider.hhs.mt.gov/pdf/pharmacy.pdf (describing how prescription reimbursement will only be denied on the basis of prescription being "not medically accepted" if determined so "by the [Montana] Department [of Public Health & Human Services] in consultation with federal guidelines, [the Montana Medicaid] DUR Board, *or* the Department medical and pharmacy consultants[]") *and* Ex.22, Montana Medicaid Preferred Drug List at 5, *available at* http://medicaidprovider.hhs.mt.gov/pdf/current/mtupdatedpdlcurrent.pdf (listing TriCor under "Cardiovascular" set of preferred agents).

that the reimbursement requests were false claims. Without alleging the existence of a false or fraudulent claim, Relator has failed to state a claim under the FCA.

III. RELATOR FAILS TO ALLEGE WITH PARTICULARITY THAT ABBOTT CAUSED FALSE CLAIMS TO BE SUBMITTED FOR REIMBURSEMENT

Relator further fails to state a claim because she does not satisfy the requirements of Rule 9(b). The Third Circuit requires FCA plaintiffs to plead their claims in accordance with the particularity requirement imposed by Rule 9(b), which states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." *See Wilkins*, 659 F.3d at 301 n.9 (citing *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs.*, 149 F.3d 227, 234 (3d Cir. 1998)). As most circuit courts have held, and the Third Circuit suggested in *Wilkins*, to satisfy Rule 9(b) in a FCA case, Relator must at least identify a representative example of a *specific* false claim actually submitted to the Government. Relator utterly fails to do so. In any event, Relator cannot meet any standard of particularity because she does not allege "'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998-99 (9th Cir. 2010) (quoting *United States ex rel. Grubbs v. Ravikumar Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)).

A. Relator Fails to Allege a Single Specific False Claim That Was Submitted to the Government for Reimbursement and Thus Cannot Satisfy Rule 9(b).

Although a party need not identify a specific false claim to be able to state a claim under Rule 12(b)(6), "the question of whether a plaintiff, at the pleading stage, must identify representative examples of specific false claims that a defendant made to the Government in order to plead an FCA claim properly *is a requirement under the more particular pleading standards of Rule 9(b)*." *Wilkins*, 659 F.3d at 308 (emphasis added). The majority of circuits to

consider the issue have concluded that the plaintiff must identify representative examples. *See United States ex rel. Bledsoe v. Cmty. Health Sys.*, 501 F.3d 493, 510 (6th Cir. 2007); *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 557 (8th Cir. 2006); *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 233 (1st Cir. 2004); *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1312 n.21 (11th Cir. 2002). As one court put it, identification in the complaint of a false claim "is the *sine qua non* of a False Claims Act violation." *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 727 (10th Cir. 2006). Here, Relator has not only failed to identify "representative examples," *she has not identified even one*. That is not sufficient, as courts within this circuit have routinely found. *See United States ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 121 (W.D. Pa. 2006); *United States ex rel. Schmidt v. Zimmer, Inc.* ("*Zimmer* II"), No. 00–1044, 2005 WL 1806502, at *3 (E.D. Pa. July 29, 2005).[15] Rule 9(b)'s particularity requirement means that Relator must "plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into" the allegations underlying her FCA claims. *United States v. Education Mgmt. Corp.*, No. 07-CV-461, 2012 WL 1658482, at *7 (W.D. Pa. May 11, 2012). Having failed to do so, Relator's claims must be dismissed under Rule 9(b).

B. Relator Fails to Plead Facts Providing Particular Details of a Scheme to Actually Submit False Claims.

As noted above, some courts have permitted FCA claims to proceed absent allegations of a specific false claim. *See United States ex rel. Budike v. PECO Energy, et al.*, No. 07-4147, 2012 WL 4108910, at *11-12 (E.D. Pa. Sept. 14, 2012) (noting division and collecting cases).

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[15] *See also United States ex rel. Piacentile v. Sanofi Synthelabo, Inc.*, No. 05-2927 (KSH), 2010 WL 5466043, at *7-8 (D.N.J. Dec. 30, 2010) (concluding relator's complaint failed under Rule 9(b) because it failed to allege a specific claim and failed even under the more lenient standard of pleading "reliable indicia that lead to a strong inference that claims were actually submitted").

While the better approach is that alluded to by the Third Circuit in *Wilkins* and applied by the majority of circuits as discussed above, the *Wilkins* court had no opportunity to definitively resolve the issue as the district court in that case had not applied Rule 9(b) at all. *See Wilkins*, 659 F.3d at 308. In any event, even those courts that have not required particularized allegations of a specific false claim nonetheless have required particularized factual information regarding the "who, what, when, where, and how" of the alleged scheme. Relator's Complaint, which relies solely on vague and conclusory allegations, is utterly insufficient.

Courts that have permitted FCA claims to proceed even absent allegations of a specific false claim necessarily require "alternative means of injecting precision and some measure of substantiation into the pleadings," *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, No. 04-186, 2006 WL 2642518, at *7 (W.D. Pa. Sept. 13, 2006) (internal quotation marks omitted), such as "particular details of a scheme to submit false claims" in combination with "reliable indicia that lead to a strong inference that claims were actually submitted," *Piacentile*, 2010 WL 5466043, at *8 (quoting *Grubbs*, 565 F.3d at 190). Relator falls far short of even this standard. Indeed, while the Complaint contains numerous allegations that purport to show a scheme to engage in off-label marketing of TriCor, Relator has pled almost no facts, beyond conclusory allegations, to support the critical element of all FCA actions: the actual submission of false claims to the government for payment.

First, the Complaint completely fails to allege facts to illustrate how, where, and when the alleged off-label promotion actually "***caused***" any physician to prescribe TriCor for an off-label use. *See Piacentile*, 2010 WL 5466043, at *8 (concluding that relator's allegations were insufficient under Rule 9(b) where the complaint only asserted in a conclusory manner that defendant's conduct led to physicians submitting improper claims). Relator provides no facts

establishing her personal knowledge that Abbott allegedly marketed TriCor off-label to physicians—particularly to physicians on whom she did not call—or that these physicians then prescribed TriCor for off-label uses as a result of the marketing activity. *See id.* (noting the complaint was insufficient where it made no mention of how the relator knew the drugs were used off-label). Simply asserting these facts to be true based on her information and belief is insufficient under Rule 9(b). *See Zimmer* II, 2005 WL 1806502, at *3 & n.6. Instead, Relator "must set forth the facts on which his belief is founded." *Id.* (citing *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004)). She has not done so.

Nor does Relator "identify the speaker of the allegedly fraudulent statements." *United States ex rel. Wilkins v. United Health Group, Inc.* ("*Wilkins* II"), No. 08-3425 (RBK/HS), 2011 WL 6719139, at *2 (D.N.J. Dec. 20, 2011) (quoting *Klein v. Gen. Nutrition Co.*, 186 F.3d 338, 345 (3d Cir. 1999)); *see also United States ex rel. Thomas v. Siemens AG*, 708 F. Supp. 2d 505, 511 (E.D. Pa. 2010) ("Rule 9(b) requires a plaintiff to identify the source of the allegedly fraudulent misrepresentation or omission."). Relator avers generally that Abbott or Abbott sales representatives engaged in off-label marketing. (*E.g.,* Am. Compl. ¶¶ 65, 67, 69, 71, 134-35.) However, she never states with any specificity the actual speaker(s) of any purported fraudulent statement nor does she identify who submitted the allegedly false claims. *Compare Zimmer* II, 2005 WL 1806502, at *3 (relator's failure to identify which of the hospitals actually submitted false claims to Medicare was fatal to the complaint) *with Budike*, 2012 WL 4108910, at *10 (holding that relator had satisfied the "who" requirement by alleging the specific employee that acted on behalf of the defendant to perpetrate the fraud). By failing to allege the "who" for even a single instance of the alleged fraudulent scheme, Relator has failed to satisfy the requirements of Rule 9(b).

Relator also fails to plead a factual basis to support a conclusion that the vaguely alleged claims were actually submitted to government healthcare programs. Nowhere in the Complaint does Relator provide information regarding how claims for reimbursement of TriCor are submitted, even as a general matter. Courts in similar cases have found FCA complaints insufficient as a matter of law where they fail to identify or explain how allegedly false claims were submitted, the content of the allegedly false submissions, or the forms or entities involved. *See, e.g., United States ex rel. Rostholder v. Omnicare, Inc.*, No. CCB-07-1283, 2012 WL 3399789, at *15 (D. Md. Aug. 14, 2012) ("Relator, however, has not sufficiently explained the nature of this process or directed the court to the specific regulations, guidance manuals, or specific forms that are used in the payment process—much less copies of the specific forms that requested reimbursement for the [particular] drugs at issue."); *see also United States v. Infomedics, Inc.*, 847 F. Supp. 2d 256 (D. Mass. 2012) (dismissing FCA healthcare case for failure to satisfy Rule 9(b) where relator relied on conclusory allegations of physician practice base and prescription numbers and failed to allege critical steps in causal chain including details of claims, details regarding pharmacists as actual submitters of claims, and patient identities).

In a feeble gesture towards providing the required factual basis for Relator's conclusory allegations, the Complaint simply lists the names of various physicians to whom Abbott allegedly marketed TriCor for off-label use and who then allegedly prescribed TriCor to diabetics or as an add-on therapy to patients already taking statins. (Am. Compl. ¶¶ 134-36.)[16] Not once, however, does Relator allege—even in a conclusory manner—that any of these

[16] At least one physician who allegedly prescribed TriCor for off-label use is not on the list of the physicians to whom Abbott allegedly marketed and promoted TriCor for off-label use, so Abbott's alleged conduct could not have had anything to do with the physician's alleged prescribing decisions. (*Compare* Am. Compl. ¶ 134 *with* ¶¶ 135-36.)

prescriptions ultimately were reimbursed by the government. (*Id.*) This is a fatal flaw: Simply because a physician wrote a prescription does not mean that the prescription was reimbursed by a federal healthcare program—a threshold requirement for a claim under the FCA. *See Zimmer* II, 2005 WL 1806502, at *3 (relator's failure to identify which of the hospitals actually submitted false claims to Medicare was fatal to the complaint). Rather, the prescription could have been paid for by other means, including through private insurance or out-of-pocket by the patient—if it was filled at all. *See United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 443 (3d Cir. 2004) (noting that "it is impossible to rule out the chance that [the allegedly improper claims] were paid for by non-Medicaid sources").

The most that can be said of the allegations in the Complaint is that they could support speculation that off-label messages *may* have been delivered to certain physicians who *may* have written prescriptions for TriCor, but the Complaint provides no details that would create a strong inference that false claims for reimbursement were ultimately submitted to the federal government. This is insufficient under Rule 9(b). Evaluating the adequacy of similar allegations, the First Circuit held:

> At most, [the relator] raises facts that suggest fraud was possible; but the complaint contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility. It may well be that doctors who prescribed Genetropin for off-label uses as a result of Pharmacia's illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed Genetropin for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it. [The relator] did not plead enough to satisfy the concerns behind Rule 9(b).

United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 733 (1st Cir. 2007).

Aware of the Complaint's shortcomings, Relator instead relies on a bare assertion that "a substantial percentage" of TriCor prescriptions were surely paid for by government programs.

(Am. Compl. ¶ 17.) This generic allegation is insufficient to rescue the Complaint. Indeed, courts have routinely rejected such attempts to rely on generalized allegations that a certain proportion of claims "must have" ended up being submitted to government programs. *See, e.g., Quinn*, 382 F.3d at 440 ("[A] False Claims Act plaintiff cannot merely describe a private scheme in detail but then allege simply and without any stated reason for his belief that claims requesting illegal payments must have submitted, were likely submitted or should have been submitted to the Government.") (quotation marks and alterations omitted); *Piacentile*, 2010 WL 5466043, at *8 (noting that relator's "allegations of the claims that were submitted to the government are conclusory, as are his allegations that the doctors actually prescribed Aventis's and Sanofi's drugs off-label to patients covered by government health programs"); *Zimmer* II, 2005 WL 1806502, at *3 (holding that a relator "may not simply hypothesize that, based on [the defendant's] allegedly illegal marketing scheme, false claims must have been submitted") (footnote omitted).

In sum, Relator's failure to identify a particular claim or group of claims, to provide specifics regarding the "who, what, where, when and how" of the alleged fraudulent scheme, or to provide a factual basis to support a "strong inference" that there was a fraudulent scheme that caused the submission of false claims to government healthcare programs for payment dooms her Complaint under the heightened pleading standard of Rule 9(b). Accordingly, the Complaint must be dismissed.

C. Relator's Allegations of a Nationwide Scheme are Insufficient Under Rule 9(b).

Relator claims that Abbott engaged in "an illegal nationwide, coordinated and deceptive scheme of false and misleading promotion and marketing of Tricor," Am. Compl. ¶ 5, and on

this basis, without restriction, she seeks damages for *all* allegedly false claims submitted to federal health insurance programs, *see id*. ¶¶ 167, 173. Again, Relator's claims are insufficient under Rule 9(b)'s pleading standard. Where the conduct alleged in an FCA complaint is limited to a particular area or facility with which the Relator is familiar, the allegations are insufficient to sustain a claim of nationwide conduct under Rule 9(b). *See, e.g.*, *United States ex rel. Harris v. Alan Ritchey, Inc.*, No. COO-2191Z, 2006 WL 3761339, at *6 (W.D. Wash. Dec. 20, 2006) (dismissing under Rule 9(b) federal FCA claims based on generalized allegations of misconduct at defendant's facilities outside of Auburn, Washington, where entirety of particularized allegations in Complaint related to Auburn, Washington facility); *United States v. Medtronic, Inc.*, Nos. 95-1236-MLB, 96-1309-MLB, 2000 WL 1478476 (D. Kan. July 13, 2000).

Here, Relator's failure to allege conduct occurring outside of Florida dooms her claims based on conduct outside of Florida. Despite asserting a "nationwide" scheme, in her 435-paragraph Complaint, Relator fails to allege *any* specific conduct—let alone misconduct—by Abbott in *any* state other than Florida. For example, the Complaint contains conclusory allegations regarding alleged conduct that took place in Relator's sales territory—which was limited to certain areas of Florida, Am. Compl. ¶ 35—but fails to provide any particularized allegations, or even generalized allegations beyond Relator's "information and belief," for her claim that the alleged conduct occurred anywhere else. (*See, e.g.*, Am. Compl. ¶¶ 115-16, 123-24 (allegations regarding conduct solely within Relator's "territory" and "sales region" in Florida); ¶ 117 (attempting without any supporting allegations to extend conduct described in ¶ 116 to entire "country" "[u]pon information and belief[]").) Thus, even if Relator has properly stated claims under the FCA—which she has not—her failure to plead particularized allegations to support the "nationwide" character of the alleged misconduct requires dismissing Counts I and

II for failure to satisfy the pleading standards of Rule 9(b) to the extent those counts are based on speculative claims of off-label promotion beyond Florida. *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 723 (N.D. Tex. Mar. 9, 2011) (dismissing multiple state FCA claims for failure to sufficiently plead facts related to conduct in states outside of the state in which the relator worked).

IV. RELATOR SEEKS TO IMPOSE FALSE CLAIMS ACT LIABILITY ON SPEECH PROTECTED BY THE FIRST AMENDMENT.

Relator's FCA claims based on her off-label promotion allegations fail for an additional reason. Even if the allegations were taken as true—which they should not be, both because they are inconsistent with the FDA-approved labeling, and because they are not alleged with particularity as required by Rule 9(b)—basing FCA liability on those allegations would impermissibly burden Abbott's speech, which is protected under the First Amendment. *See, e.g., Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761, 770 (1976) (recognizing that commercial speech, such as the advertisement of drug prices, was protected by the First Amendment and dismissing suggestion that drug pricing could be regulated in order to protect unwitting consumers). Indeed, the Supreme Court has "rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with that information." *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 374 (2002) (holding that provisions of the Food and Drug Administration Modernization Act regulating the advertisement of "drug compounding" ran afoul of the First Amendment's protection of commercial speech). Thus, in *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2670-72 (2011), the Supreme Court declared unconstitutional a Vermont law restricting the sale, disclosure, and use

of pharmacy records revealing the prescribing practices of doctors that were used specifically for marketing purposes by pharmaceutical manufacturers to promote their drugs in a targeted fashion. In so doing, the Supreme Court specifically recognized the benefits of pharmaceutical marketing, noting that "[i]f pharmaceutical marketing affects treatment decisions, it does so because doctors find it persuasive." *Id.* at 2670.

This body of Supreme Court precedent necessarily protects off-label promotion based on information reasonably believed to be truthful. *See id*; *see also id*. at 2675–76 (Breyer, J., dissenting) ("the same First Amendment standards that apply to Vermont here [under the majority opinion's analysis] would apply to similar regulatory actions taken by other States or by the Federal Government acting, for example, through Food and Drug Administration (FDA) regulation"). Because Relator's allegations of off-label promotion, even if taken as true, would constitute protected speech under the First Amendment, Relator may not permissibly base her FCA claims upon such speech. "Imposition of civil liability, such as the award of money damages, is treated no less stringently than direct regulation of speech . . . ." *In re Orthopedic Bone Screw Prods. Liability Litig.*, 193 F.3d 781, 792 (3d Cir. 1999); *see Boehner v. McDermott*, 484 F.3d 573, 579–80 (D.C. Cir. 2007) (explaining that "[i]f [the defendant] had the [First Amendment] right, . . . neither the House nor the courts could impose sanctions on him for exercising it"). That is because "[c]omplaints based on speech protected by the First Amendment have far-ranging and deleterious effects, and the mere threat of civil liability can cause potential defendants to 'steer far wider of the unlawful zone'." *Monteiro v. Tempe Union High School Dist.*, 158 F.3d 1022, 1029 (9th Cir. 1998). Indeed, "'[t]he fear of damage awards . . . may be markedly more inhibiting than the fear of prosecution under a criminal statute.'" *In re Orthopedic Bone Screw*, 193 F.3d at 792 (alteration in original) (quoting *New York Times Co. v.*

Sullivan, 376 U.S. 254, 279–280 (1964)). Thus, civil liability cannot permissibly be imposed for Abbott's alleged "off-label" marketing and promotional messages and statements to healthcare professionals regarding TriCor.

V. THE COMPLAINT FAILS TO STATE A CLAIM OR TO PROPERLY PLEAD A VIOLATION OF THE FALSE CLAIMS ACT BASED ON ILLEGAL KICKBACKS.

Relator supplements her primary theory of FCA liability, based on off-label promotion, with conclusory allegations that Abbott provided "lunches, dinners, trips to resorts for conferences, theater programs, professional football games and concerts[,]" Am. Compl. ¶ 125, "praceptorship[]" programs, *id*. ¶ 128, and "Advisory Board Meetings," *id*. ¶ 129, to physicians, resulting in the submission of "many thousands" of claims to government healthcare programs, *id*. ¶ 3. Relator's underlying legal theory appears to be that meals, activities, and conferences were allegedly provided to encourage physicians to prescribe TriCor in violation of the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, and that this conduct caused claims based on violations of the AKS, which are not lawfully reimbursable, to be submitted. (*See* Am. Compl. ¶ 10, 165, 171.)[17]

Relator's allegations based on this theory fail to satisfy the particularity requirement of Rule 9(b).[18] As discussed above, most courts have held, and this circuit has suggested, that Rule

[17] The AKS provides in relevant part that "[w]hoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind[]. . . in return for . . . ordering[] or arranging for ***or*** recommending purchasing[]. . . or ordering any good[]. . . or item for which payment may be made . . . under Federal health care program[s] shall be guilty of a felony . . . ." 42 U.S.C. § 1320a-7b(b)(1) (emphasis added).

[18] The Rule 9(b) pleading standard of course applies to FCA actions. *See Zimmer* II, 2005 WL 1806502. Where, as here, the theory of FCA liability is premised on subsidiary allegations that the defendant violated various statutes (such as the AKS), Rule 9(b) also applies to the subsidiary

9(b) requires Relator to identify a representative example of a *specific* claim or claims that are allegedly fraudulent. *See supra* Section III.A., *Wilkins*, 659 F.3d at 308. And, regardless, even those courts that allow relators to proceed without identifying a specific claim still require "particular details of a scheme to submit false claims," *Singh*, 2006 WL 2642518, at *7, in combination with "reliable indicia that lead to a strong inference that claims were actually submitted," *Piacentile*, 2010 WL 5466043, at *8 (quoting *Grubbs*, 565 F.3d at 190). Relator has not done so, and this failure is itself sufficient grounds to dismiss Relator's claims based on alleged AKS violations.

The Complaint offers very few factual allegations to support the existence of what Relator labels "illegal kickbacks," and these allegations certainly fail to comply with the pleading standards of Rule 9(b). (*See* Am. Compl. ¶¶ 120-29.) Relator does not identify a single allegedly false claim nor does she identify the "who, what, when, where and how of the events at issue." *In re Rockefeller Ctr. Props., Inc.*, *Secs. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (quotations omitted). Indeed, not *one* individual is identified as having actually engaged in any of the conduct alleged; not *one* physician is identified as having actually received any of these supposed "kickbacks"; not *one* date, or even a range of time, is identified during which this supposed conduct took place; not *one* place is identified where any of this conduct occurred; not *one* pharmacist is identified as having filled a prescription for TriCor because of any of this alleged kickback activity; not even *one* claim is identified as having ever actually been submitted to a healthcare program. In addition to her failure to identify any particularized incidents or programs, Relator also fails to provide any other details of the putative "scheme" directed at any

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allegations of statutory violation. *See, e.g.*, *Wilkins* II, 2011 WL 6719139, at *1 (applying Rule 9(b) to alleged AKS violation underlying alleged FCA violation).

alleged improper inducements or remuneration. Nor does she provide any other details of the implementation of the alleged fraudulent campaign.

Instead, Relator relies on vague, generalized accusations that illegal remuneration was offered to unspecified physicians. (*See, e.g.*, Am. Compl. ¶¶ 122, 124, 129 (generically alleging that "doctors who wrote a large number of prescriptions" were targeted, that "Abbott [provided] . . . physicians [with] lunches, dinners, [and] trips [to events,]" and that alleged inducements disguised as meetings were held in "vacation cities")). These allegations are plainly insufficient "to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior," let alone to allow Abbott to "muster[] a full defense." *United States ex rel. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430, 437 (E.D. Pa. 2004) (quoting *United States ex rel. Atkinson v. Pennsylvania Shipbuilding Co.*, No. 94-7316, 2000 WL 1207162, at *8 (E.D. Pa. Aug. 24, 2000)). Rather, the allegations related to kickbacks are precisely the sort of "spurious charges of immoral and fraudulent behavior" that Rule 9(b) is designed to prevent. *Id.*; *see, e.g.*, *Wilkins* II, 2011 WL 6719139, at *3 (dismissing portion of FCA case premised on AKS violations where Relator failed to provide "date, place or time," of any of the alleged kickback conduct or to otherwise inject precision into kickback allegations) (quoting *Lum v. Bank of Am.*, 361 F.3d 217, 223-24 (3d Cir. 2004)); *United States ex rel. Bartlett v. Tyrone Hospital, Inc.*, 234 F.R.D. 113, 125 (W.D. Pa. 2006) (dismissing portion of FCA case premised on AKS violations "due to . . . lack of compliance with Rule 9(b) as to allegations of the actual submission of false claims . . . to the government[]"). Thus, even if the conduct as alleged did qualify as "kickback" activity,

Relator's allegations here fail to meet the standard of particularity required under Rule 9(b) and must be dismissed.[19]

Relator also fails to plead with any particularity a connection between the alleged kickbacks and the filing of any false claims—the *sine qua non* of FCA liability, *see Zimmer* II, 2005 WL 1806502, at *2 (citing *United States ex rel. Clausen v. Lab Corp. of America,* 290 F.3d 1301, 1311 (11th Cir. 2002))—that would make these kickback allegations relevant to an action under the FCA. As with her off-label promotion allegations, Relator simply fails to allege any *facts* regarding how the "many thousands" of false claims allegedly engendered by Abbott's "kickback scheme" were actually submitted to the federal government, even as a general matter. Courts faced with similarly deficient allegations by relators that fail to describe at even a rudimentary level the means by which claims are submitted to the government have found the FCA complaints at issue insufficient as a matter of law. *See, e.g.*, *Rostholder*, 2012 WL

[19] Though the overwhelmingly vague and conclusory nature of Relator's allegations requires the dismissal of this portion of Relator's Complaint under Rule 9(b), many of Relator's allegations describe facially proper conduct and thus would fail to state a claim under Rule 12(b)(6) even if, contrary to fact, Relator had pleaded such allegations with particularity. Drug manufacturers are permitted to sponsor speaking events, roundtables, and preceptorships within certain guidelines, and manufacturers sponsor such programs routinely. *See generally* Ex. 23, HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003). The AKS explicitly excludes from its scope conduct that is carried within HHS-sanctioned guidelines, such as the Compliance Program Guideline for Pharmaceutical Manufacturers cited above. *See* 42 U.S.C. § 1320(a)-7b(3)(D) (the penalty provisions of the AKS "shall not apply to . . . any payment practice specified by the Secretary [of HHS] in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or in regulations under section 1395w-104(e)(6) of this title."). Therefore, to the extent Relator merely alleges run-of-the-mill practices that comply with HHS-OIG guidelines, she cannot allege a violation of the AKS, and any FCA claim premised on such conduct fails to state a claim. To the extent that Relator relies on conduct that fell outside the protected zone of activity provided by the HHS-OIG Guidelines, the Complaint fails under Rules 9(b) and 12(b)(6) because it offers no factual allegations to show that any particular instance of such alleged programming sponsored by Abbott ran afoul of those guidelines such as to become unlawful.

3399789, at *15; *see also Infomedics*, 847 F. Supp. 2d 256. Similarly, Relator also fails to allege—even in a conclusory manner—that any prescription written because of Abbott's alleged misconduct (*i.e.* the alleged "kickback scheme") was ultimately reimbursed by the federal government. Here, Relator fails to identify even *one* physician who allegedly was targeted for these "kickbacks"—let alone associate particular physicians with particular allegations of misconduct.

Because Relator has failed to identify the "who, what, when, where and how" of the alleged kickback conduct and, because Relator has failed to allege even one specific false claim or, in the alternative, to identify the "who, what, when, where and how" connecting the alleged kickback conduct to the submission of false claims, Relator's Counts I and II should be dismissed for failure to satisfy the Rule 9(b) pleading standard to the extent they are premised on allegations of kickback conduct and resulting submission of false claims to the government.

VI. RELATOR'S FEDERAL CLAIMS ARE BARRED IN PART BY THE APPLICABLE STATUTE OF LIMITATIONS.

Actions under the FCA are subject to a statute of limitations of six years. 31 U.S.C. § 3731(b)(1). The limitations period begins to run on the date that the first request for payment is allegedly made. *United States ex rel. Bauchwitz v. Holloman*, 671 F. Supp. 2d 674, 686 (E.D. Pa. 2009).[20] The Complaint inconsistently identifies the time period it purports to cover, sometimes asserting that false claims began in 2000, *see, e.g.*, Am. Compl. ¶ 275, and sometimes asserting that false claims began in 2002, *see, e.g.*, *id*. ¶¶ 68, 87. In any event, because Relator filed her complaint on September 18, 2009, the applicable six-year statutory limitations period

[20] This Court has held that "the three-year tolling period in [31 U.S.C.] § 3731(b)(2) does not apply in cases where the government does not intervene." *Bauchwitz*, 671 F. Supp. 2d at 694-95. Accordingly, Relator's Complaint is necessarily subject to 31 U.S.C. § 3731(b)(1).

requires that Counts I and II be dismissed to the extent they relate to alleged false claims submitted prior to September 18, 2003.

VII. RELATOR'S STATE LAW CLAIMS SHOULD BE DISMISSED.

In addition to Relator's federal FCA claims, she also alleges that Abbott violated the false claims acts of twenty-two states and the District of Columbia (along with related fraud statutes in two of the twenty-two states)[21] by engaging in the same alleged conduct underlying the FCA claims during the same vaguely-defined period of time. (*See* Am. Compl. ¶¶ 174-435 (Counts Three – Count Twenty-Eight).)

As a threshold matter, this court should decline to exercise supplemental jurisdiction over the state law claims in the event the federal claims are dismissed.[22] *See Burns v. Lavender Hill*

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[21] This includes Count Fourteen, Am. Compl. ¶¶ 272-280 (alleging second statutory violation of Tennessee law) ("Tennessee II") and Count Twenty-One, Am. Compl. ¶¶ 331-341 (alleging second statutory violation of New Mexico law) ("New Mexico II"). However, it *excludes* Count Twenty-Three, Am. Compl. ¶¶ 351-363. Count Twenty-Three appears to be duplicative of Count Twenty-Two, Am. Compl. ¶¶ 342-350. Count Twenty-Two asserts a violation of Michigan's Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.* (2009). Count Twenty-Three is titled "Violation of Michigan Public Acts, 1977 PA 72, as amended by 1984 PA 333[,] as amended by 2005 PA 337, as amended by 2008 PA 421[.]" This heading appears to be a reference to the legislation that enacted and then subsequently amended Michigan's Medicaid False Claims Act, *i.e.*, the very same statute already invoked in Count Twenty-Two. *See* 1977 Mich. Pub. Acts. No. 72 (enacting the Michigan Medicaid False Claims Act); 1984 Mich. Pub. Acts. No. 333 (amending the same); 2005 Mich. Pub. Acts. No. 337 (amending the same); 2008 Mich. Pub. Acts. No. 421 (amending the same); *see also* Am. Compl. ¶¶ 352 (acknowledging Count Twenty-Three is brought "[u]nder the Michigan Medicaid False Claims Act"). Pursuant to Fed. R. Civ. Proc. 12(f)(2), Count Twenty-Three should therefore be struck as literally duplicative and redundant of Count Twenty-Two. *See, e.g.*, *Garlanger v. Verbeke*, 223 F. Supp. 2d 596, 609 (D.N.J. 2002) (striking multiple counts of complaint "[i]n the interests of streamlining the pleadings and removing . . . redundant clutter[]"). In the extraordinary alternative that Relator maintains that, in fact, Count Twenty-Three is not redundant of Count Twenty-Two, the Complaint fails to satisfy Fed. R. Civ. Proc. 8(a)(2) and thus would have to be pleaded more definitively pursuant to Fed. R. Civ. Proc. 12(e). *See Holmes v. Gates*, 403 F. App'x 670 (3d Cir. 2010).

[22] All uses of the term "state" should be read as including the District of Columbia unless otherwise noted.

Herb Farm, Inc., No. 01-7019, 2005 WL 1006321, at *5 & n.45 (E.D. Pa. Apr. 28, 2005) ("Where 'the claim over which the district court has original jurisdiction is dismissed before trial, the district court *must* decline to decide the pendent state law claims unless considerations of judicial economy, convenience, and fairness to the parties provide an affirmative justification for doing so.'") (quoting *Borough of W. Mifflin v. Lancaster*, 45 F.3d 780, 788 (3d Cir. 1995)) (emphasis added). Courts in this Circuit normally refuse to exercise supplemental jurisdiction over state FCA claims once the federal FCA claims are dismissed. *See, e.g.*, *Garg v. Covanta Holding Corp.*, No. 11-3174, 2012 WL 1609003, at *2, *5 (3d Cir. Apr. 17, 2012) (affirming judgment of district court dismissing federal FCA claim and, in light of dismissal of federal claims, declining to exercise supplemental jurisdiction over remaining state law claim); *United States ex rel. Schumann v. AstraZeneca PLC*, No. 03-5423, 2010 WL 4025904, at *7, *11 (E.D. Pa. Oct. 13, 2010) (dismissing federal healthcare FCA claims premised on illegal remuneration and price reporting fraud and, in light of dismissal, declining to exercise supplemental jurisdiction over remaining state healthcare FCA claims); *cf. Dookeran v. Mercy Hosp. of Pittsburg*, 281 F.3d 105, 106-107 (3d Cir. 2002) (affirming judgment of district court granting summary judgment against federal healthcare FCA retaliation claim and, in light of summary judgment, declining to exercise supplemental jurisdiction over remaining state healthcare FCA retaliation claims); *Burns v. Lavender Hill Herb Farm, Inc.*, No. 01-CV-7019, 2002 WL 31513418, at *2, *9 (E.D. Pa. Oct. 30, 2002) (dismissing, *inter alia*, federal FCA claims and, in light of dismissal, declining to exercise supplemental jurisdiction over remaining state law claims).

In any event, Relator's state law claims fail as a matter of law because they are barred for the following reasons: (a) Relator has failed to plead them with particularity as required by Rule

9(b); (b) they fail for the same reasons Relator's federal FCA claims fail as a matter of law because many of the state statutes at issue are patterned on the FCA; (c) certain states chose not to intervene in or otherwise act regarding Relator's lawsuit as required by an asserted statute; (d) in many cases the statutory provisions relied upon were not in effect at the time the alleged misconduct occurred and do not apply retroactively as a matter of state law; (e) many of Relator's claims are barred by the applicable statute of limitations; (f) Relator lacks standing to bring suit (Count Twenty—New Mexico I); or is prohibited from bringing suit under the asserted statute (Count Fourteen—Tennessee II).

State (Count) ↓ Basis →	**Failure to Satisfy Rule 9(b)**	**For Same Reasons Federal Counts Fail**	**Failure by State to Intervene or Otherwise Act**	**Impermissible Retroactive Application of State Law**	**Statute of Limitations**	**Other**
Illinois (Count Three)	✓	✓			✓	
California (Count Four)	✓	✓				
Delaware (Count Five)	✓	✓	✓	✓	✓	
District of Columbia (Count Six)	✓	✓			✓	
Florida (Count "Eight" [*sic*])	✓	✓			✓	
Georgia (Count Eight)	✓	✓		✓	✓	
Hawaii (Count Nine)	✓	✓		✓	✓	
Louisiana (Count Ten)	✓				✓	
Massachusetts (Count Eleven)	✓	✓		✓	✓	
Montana (Count Twelve)	✓	✓		✓	✓	
Tennessee I (Count Thirteen)	✓	✓			✓	

State (Count) ↓ / Basis →	Failure to Satisfy Rule 9(b)	For Same Reasons Federal Counts Fail	Failure by State to Intervene or Otherwise Act	Impermissible Retroactive Application of State Law	Statute of Limitations	Other
Tennessee II (Count Fourteen)	✓			✓		Statutory prohibition
Texas (Count Fifteen)	✓	✓	✓			
Virginia (Count Sixteen)	✓	✓		✓	✓	
Indiana (Count Seventeen)	✓	✓		✓	✓	
Nevada (Count Eighteen)	✓	✓			✓	
New Hampshire (Count Nineteen)	✓		✓	✓	✓	
New Mexico I (Count Twenty)	✓	✓	✓	✓		Relator is not an "affected person"
New Mexico II (Count Twenty-One)	✓	✓		✓		
Michigan I (Count Twenty-Two)	✓				✓	
Michigan II (Count Twenty-Three)	N/A	N/A	N/A	N/A	N/A	Duplicative pleading
New York (Count Twenty-Four)	✓	✓		✓		
Oklahoma (Count Twenty-Five)	✓	✓		✓	✓	
Wisconsin (Count Twenty-Six)	✓			✓		
Rhode Island (Count Twenty-	✓	✓		✓	✓	

State (Count) ↓ / Basis →	Failure to Satisfy Rule 9(b)	For Same Reasons Federal Counts Fail	Failure by State to Intervene or Otherwise Act	Impermissible Retroactive Application of State Law	Statute of Limitations	Other
Seven)						
New Jersey (Count Twenty-Eight)	✓	✓		✓	✓	

A. Relator's State Law Claims Fail to Satisfy Rule 9(b)'s Particularity Requirements.

As an initial matter, Relator's state-law claims must be dismissed because they are not pled with particularity. Each of the state-law claims includes fraud as an element of the action. Thus, Rule 9(b) applies. *See Universal Commc'n Sys., Inc. v. Lycos, Inc.*, 478 F.3d 413, 427 (1st Cir. 2007) (quoting *Hayduk v. Lanna*, 775 F.2d 441, 443 (1st Cir. 1985)); *see also* 5A Wright & Miller, *Federal Practice and Procedure* § 1297 (3d ed. 2004)). However, just as she has failed to plead her federal claims with particularity, Relator has failed to allege the "who, what, when, where and how" of her state-law claims. As such, those claims must be dismissed.

B. Relator's Claims Should Be Dismissed for the Same Reasons Relator's Claims Fail Under the Federal False Claims Act.

The following state law statutes invoked in Relator's Complaint contain language that mirrors the federal False Claims Act: California, Georgia, Illinois, Massachusetts, New Mexico, New York, Delaware, the District of Columbia, Florida, Hawaii, Nevada, Tennessee, Texas, Virginia, Indiana, Montana, New Jersey, Oklahoma, and Rhode Island.[23] These states look to the

[23] *See New York v. Amgen, Inc.*, 652 F.3d 103, 108-09 (1st Cir. 2011) (recognizing that state false claims acts for California, Georgia, Illinois, Indiana, Massachusetts, New Mexico, and New York mirror the federal FCA); *United States ex rel. Rost v. Pfizer, Inc.*, 446 F. Supp. 2d 6, n.13 (D. Mass. 2006) (recognizing that state false claims acts for California, Delaware, the District of Columbia, Florida, Hawaii, Illinois, Massachusetts, Nevada, Tennessee, Texas, and Virginia mirror the federal FCA); *United States ex rel. Nudelman v. Intl Rehab. Assoc., Inc.*, No. 00-1837,

federal False Claims Act case law when construing their respective, analogue statutes.[24] Thus, to the extent that Relator's claims[25] fail under the federal FCA for the reasons set forth above, under Rules 12(b)(6) and 9(b), so too do her claims under the corollary state statutes.

2006 WL 925035 (E.D. Pa. 2006) (recognizing that state false claims acts for California, Delaware, Florida, Illinois, Nevada, and Tennessee mirror the federal FCA); *see also Organon USA*, 2012 WL 1997874, at *17 (noting parties' agreement that state false claims acts for California, Delaware, District of Columbia, Florida, Hawaii, Illinois, Indiana, Massachusetts, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, and Virginia mirror the federal FCA).

[24] *E.g.*, *United States ex rel. Herrera v. Bon Secours Cottage Health Servs.*, 665 F. Supp. 2d 782, 783 n.2 (E.D. Mich. 2008) ("The Michigan Medicaid False Claims Act is substantially similar to the FCA."); *United States ex rel. Woodruff v. Haw. Pac. Health*, 560 F. Supp. 2d 988, 997 n.7 (D. Haw. 2008) ("The Hawaii False Claims Act . . . is nearly identical to the federal FCA; thus, the court applies the same analysis for liability under the federal and state FCA."); *United States ex rel. Heater v. Holy Cross Hosp., Inc.*, 510 F. Supp. 2d 1027, 1033-34 n.5 (S.D. Fla. 2007) (considering the Florida FCA and federal FCA together and explaining that the Florida FCA tracks the language of, and is modeled after, the federal FCA); *United States ex rel. Stierli v. Shasta Servs., Inc.*, 440 F. Supp. 2d 1108, 1111 (E.D. Cal. 2006) ("The California False Claims Act was patterned after, and closely resembles, its federal counterpart. Because of the similarity between the two Acts, federal decisions are deemed persuasive authority in interpreting both state and federal provisions." (citation omitted)); *Nudelman*, 2006 WL 925035, at *12 ("The False Claims Acts of California, Delaware, Florida, Illinois, Nevada and the Tennessee Medicaid False Claims Act read similarly and are substantively the same as the FCA under the United States Code. Accordingly, our analysis of the federal claims shall apply equally to the states' claims." (citations omitted)); *United States ex rel. Humphrey v. Franklin-Williamson Human Servs., Inc.*, 189 F. Supp. 2d 862, 867 (S.D. Ill. 2002) (relying on federal case law for guidance on state law claims).

[25] Of the twenty-five state counts raised in Relator's Complaint (excluding Count Twenty-Three), at least twenty are based on state statutes that mirror the federal FCA. The specific counts are: Count Four (California); Count Eight (Georgia); Count Three (Illinois); Count Eleven (Massachusetts); Count Twenty (New Mexico I); Count Twenty-One (New Mexico II); Count Twenty-Four (New York); Count Five (Delaware); Count Six (the District of Columbia); Count "Eight [*sic*]" (Florida); Count Nine (Hawaii); Count Eighteen (Nevada); Count Thirteen (Tennessee I); Count Fifteen (Texas); Count Sixteen (Virginia); Count Seventeen (Indiana); Count Twelve (Montana); Count Twenty-Eight (New Jersey); Count Twenty-Five (Oklahoma); and Count Twenty-Seven (Rhode Island).

C. Where State Statutes Require Intervention or Action by the State, Relator's Claims Must Be Dismissed.

Several of Relator's state claims fail on their face because those states chose not to intervene in this lawsuit or otherwise act as required by statute to permit the relator's state FCA claim to proceed. Specifically, several of the *qui tam* statutory provisions that were in place on September 18, 2009, when Relator filed this lawsuit, preclude such actions where, as here, the given state declines to intervene or otherwise act (*e.g.*, by issuance of a written determination in lieu of intervention) as required by statute to permit a relator's state FCA claim to proceed. These states include Delaware (Count Five),[26] New Hampshire (Count Nineteen),[27] New Mexico

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[26] *See* Delaware False Claims and Reporting Act ("DCFRA"), Del. Code tit. 6, § 1203(b)(2) (effective before 2009 amendments). Although the DCFRA was amended in July 2009, the amendment only applies to suits where state FCA liability is based on conduct occurring on or after the July 2009 effective date; where, as here, the suit is based on conduct occurring before the July 2009 effective date, the pre-amendment version of the DCFRA applies. *See United States ex rel. Streck v. Allergan, Inc.*, No. 08-5135, 2012 WL 2593791, at *15-16 (E.D. Pa. July 3, 2012); *see also United States ex rel. Conrad v. GRIFOLS Biologicals Inc.*, No. RDB 07–3176, 2010 WL 2733321, at *6 (D. Md. July 9, 2010). Under the applicable version of the DCFRA, the Delaware Attorney general must conduct an investigation and make a written determination of whether there is substantial evidence that a violation of the DCFRA has occurred. *See* Del. Code tit. 6, § 1203(b)(2) (pre-amendment version). Where the State of Delaware chooses not to intervene, a relator may proceed with the action only if "the Attorney General determined that there is substantial evidence that a violation occurred." *Id.* § 1203(b)(4)(b). Here, the State of Delaware has declined to intervene and Relator has not alleged that the Attorney General issued a "substantial evidence" determination that would allow her to proceed with this action absent state intervention. Therefore, Count Five must be dismissed.

[27] *See* New Hampshire Medicaid Fraud & False Claims Act, N.H. Rev. Stat. § 167:61-c(II)(e) (effective before 2009 amendments). Although the state's false claims act was amended in June 2009, the amendment only applies to suits where state FCA liability is based on conduct occurring on or before the June 2009 effective date; where, as here, the suit is based on conduct occurring before the June 2009 effective date, the pre-amendment version of the statute applies. *See Streck*, 2012 WL 2593791, at *16. Under the applicable version of the state statute, if, as here, the state "declines to take over the action[,]" then "the action shall be dismissed[.]" N.H. Rev. Stat. § 167:61-c(II)(e) (effective before 2009 amendments).

(Count Twenty),[28] and Texas (Count Fifteen).[29] Accordingly, the Court should dismiss Relator's claims brought on behalf of those states.

D. Relator's Claims Should Be Dismissed to the Extent They Rely on the Retroactive Application of State Law.

Many of Relator's state law claims are facially defective because they depend on the impermissible retroactive application of statutes or substantive amendments to those statutes. Relator's claims are premised on alleged misconduct that took place between, at most, 2000 and 2008. (*See* Am. Compl. ¶¶ 174-435 (Counts Three *through* Twenty-Eight)). But some of the state laws at issue were not enacted until 2004 (*e.g.*, New Mexico I, Count Twenty), 2005 (*e.g.*, Montana, Count Twelve), 2007 (*e.g.*, Oklahoma, Count Twenty-Five), or even 2008 (*e.g.*, New Jersey, Count Twenty-Eight). As a result, Relator seeks to apply these statutes retroactively which, for almost every statute, is prohibited by the statute itself or by courts applying the

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[28] *See* New Mexico False Claims Act, N.M. Stat. § 27-14-7(E)(2). Where, as here, the state "declines to take over the action," a *qui tam* relator may only proceed upon a determination "that there is substantial evidence" of a statutory violation. *Id.* Realtor has not alleged that New Mexico made such a determination; therefore, this count must be dismissed. This argument does not apply to Relator's other New Mexico state law claim (Count Twenty-One) though that claim should also be dismissed at least in part for reasons discussed below. (*See infra* Section VII.D.)

[29] Until May 4, 2007, the Texas Medicaid Fraud Prevention Act ("TMFPA"), Tex. Hum. Res. Code § 36.001 *et seq.*, required dismissal of a *qui tam* lawsuit if the State of Texas did not intervene within 60 days after being served with the lawsuit. *See id.* § 36.104(b) (effective from Sept. 1, 1997 until May 4, 2007) ("If the state declines to take over the action, the court shall dismiss the action"). While the TMFPA was subsequently amended to allow *qui tam* lawsuits to proceed absent state intervention, such amendment applied "only to conduct that occurs on or after the effective date [May 4, 2007] of this Act. Conduct that occurs before the effective date of the Act is governed by the law in effect at the time the conduct occurred, and that law is continued in effect for that purpose." Texas Acts 2007, 80th Leg, Ch. 29, § 6, eff. May 4, 2007 (bracketed language in original). Here, Relator alleges that the purported conduct allegedly took place between, at most, 2000 and 2008. (*See, e.g.*, Am. Compl. ¶ 12; *see also id.* ¶ 35 (noting Relator's period of employment marketing TriCor lasted from January 2000 through January 2008); *but see, e.g.*, *id.* ¶ 68 (claiming 2002-2008 periods for alleged first-line diabetes and combination therapy off-label marketing conduct).) The State of Texas has not intervened in this case. Therefore, to the extent Count Fifteen alleges false claims on or before May 4, 2007, Relator is barred from pursuing these claims.

statute. Moreover, in addition, any such retroactive application of a state FCA statute would violate the *Ex Post Facto* Clause of the United States Constitution. (*See, e.g.*, Ex. 24, Order of Dismissal, *New Mexico ex rel. Foy v. Vanderbilt Capital Advisors, LLC*, No. D-101CV200801895 (N.M. 1st Jud. Dist. Ct. Apr. 28, 2010) (ruling that retroactive application of state FCA would violate *Ex Post Facto* Clauses of both federal and state constitutions despite explicit statutory language authorizing retroactive application).) Therefore, the Court should dismiss Relator's claims insofar as they are based on statutes that either did not exist for the full period during which Relator alleges that Abbott engaged in the misconduct at issue (*i.e.*, at most, 2000-2008) or, to the extent they did exist, did not provide for a *qui tam* cause of action for that same full period.

While none of the Relator's state law counts is entirely barred on this basis, sixteen of the twenty-five[30] state counts seek to give state statutes improper retroactive effect as they relate to past conduct. In these circumstances, the Court should dismiss Relator's counts brought under the following statutes to the extent Relator seeks to apply them to alleged conduct that occurred *before* each respective statute's relevant effective date: Delaware (Count Five) (effective date June 30, 2000);[31] Georgia (Count Eight) (effective date May 24, 2007);[32] Hawaii (Count Nine)

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[30] This excludes Count Twenty-Three for reasons discussed in footnote 22.

[31] *See* Delaware False Claims and Reporting Act, Del. Code. tit. 6, § 1201 *et seq.* (effective June 30, 2000); *see also Wilson v. Triangle Oil Co.*, 566 A.2d 1016, 1018 (Del. Super. Ct. 1989) ("[A]bsent a clear legislative intent, Delaware courts will not infer an intention to make an act retroactive."); *United States ex rel. Conrad v. Grifols Biologicals Inc.*, No. RDB 07-3176, 2010 WL 2733321, at *6 (D. Md. July 9, 2010) (holding that the 2009 amendments to the DFCRA are not retroactive).

[32] The Georgia False Medicaid Claims Act provisions on which Relators rely (*i.e.*, Ga. Code § 49-4-168 *et seq.*) did not become effective until May 24, 2007. Accordingly, the Georgia statute may not be applied retroactively to that portion of the alleged misconduct at issue in this case that occurred prior to May 24, 2007. S*ee Walker v. Willis*, 435 S.E.2d 621, 622 (Ga. Ct. App.

(effective date May 26, 2000);[33] Indiana (Count Seventeen) (effective date July 1, 2005);[34] Massachusetts (Count Eleven) (effective date July 1, 2000);[35] Montana (Count Twelve) (effective date May 1, 2005);[36] New Hampshire (Count Nineteen) (effective date January 1, 2005);[37] New Jersey (Count Twenty-Eight) (effective date March 13, 2008);[38] New Mexico I (Count Twenty) (effective date May 19, 2004);[39] New Mexico II (Count Twenty-One) (effective

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1993) ("Statutes generally are applied prospectively unless a clear contrary intention is indicated . . . .") (citing *Polito v. Holland*, 365 S.E.2d 273 (Ga. 1988).)

[33] *See* Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.* (effective May 26, 2000); *id.* Ch. 661, Pt. II, note ("This part became effective May 26, 2000").

[34] *See* Indiana False Claims and Whistleblower Protection Act, Ind. Code. § 5-11-5.5-1 *et seq.* (effective July 1, 2005); *see also State v. Pelley*, 828 N.E.2d 915, 919 (Ind. 2005) ("Statutes are to be given prospective effect only, unless the legislature unequivocally and unambiguously intended retrospective effect as well.").

[35] Statute was effective July 1, 2000. H.B. No. 5300, Mass. Legis. Serv. Ch. 159 (2000). There is no indication of an intent to make statute retroactively applicable. *See United States ex rel. King v. Solvay S.A.* ("*Solvay* I"), 823 F. Supp. 2d 472, 527-28 (S.D. Tex. 2011), *order vacated in non-relevant part on reconsideration by United States ex rel. King v. Solvay S.A.* "*Solvay* II"), No. H-06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012); *see also Commonwealth of Massachusetts v. Schering-Plough*, 779 F. Supp. 2d 224, 232-38 (D. Mass. 2011).

[36] *See* Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.* (2009). Montana's FCA became effective on May 1, 2005. *See* 2005 Mont. Laws Ch. 465 (approving Montana FCA Apr. 28, 2005 and making statute effective as of the next day). The statute lacks any express retroactivity provisions and there is thus no legally cognizable intent to make it retroactively applicable.

[37] *See* New Hampshire Medicaid Fraud & False Claims Act, N.H. Rev. Stat. § 167:61-a *et seq.* (*qui tam* provisions effective Jan. 1, 2005); 2004 N.H. Laws ch. 167, § 167:4 ("No provision of this act shall apply with respect to any claim . . . submitted prior to January 1, 2005").

[38] The New Jersey False Claims Act provisions on which Relators rely (*i.e.*, N.J. Stat. § 2A:32C-1 *et seq.*) did not become effective until March 13, 2008. Accordingly, the New Jersey statute may not be applied retroactively to the alleged misconduct at issue in this case that occurred before March 13, 2008. *See Oberhand v. Dir., Div. of Taxation*, 940 A.2d 1202, 1209 (N.J. 2008) (explaining that there is a general rule of prospective application unless the legislature expresses an intent that the statute is to be applied retroactively).

[39] *See* New Mexico False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* (effective May 19, 2004); *see also Howell v. Heim*, 882 P.2d 541, 547 (N.M. 1994) (explaining that "absent a clear intention to the contrary," New Mexico courts presume that a statute only applies prospectively).

date July 1, 2007);[40] New York (Count Twenty-Four) (effective date April 1, 2007);[41] Oklahoma (Count Twenty-Five) (effective date November 1, 2007);[42] Rhode Island (Count Twenty-Seven) (effective date July 1, 2007);[43] Tennessee II (Count Fourteen) (effective date July 1, 2001);[44]

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[40] New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-5(C) (effective July 1, 2007); Ex. 24, *New Mexico ex rel. Foy v. Vanderbilt Capital Advisors, LLC*, No. D-101-CV-2008-1895 (N.M. 1st Dist. Ct. Apr. 28, 2010) (holding that the New Mexico Fraud Against Taxpayers Act cannot be applied retroactively despite that statute's express provision for such application).

[41] New York False Claims Act, 2010 N.Y. Sess. Laws ch. 379, § 13 (effective Apr. 1, 2007, amended Aug. 27, 2010) (codified as amended at N.Y. State Fin. § 187 *et seq.*).

[42] The Oklahoma Medicaid False Claims Act provisions on which Relators rely (*i.e.*, Okla. Stat. Ann. tit. 63, § 5053 *et seq.*) did not become effective until November 1, 2007. Accordingly, the Oklahoma statute may not be applied retroactively to the alleged misconduct at issue in this case occurring before November 1, 2007. *See CAN Ins. Co. v. Ellis*, 148 P.3d 874, 877 (Okla. 2006) (holding that disagreement regarding whether a statute applies retroactively "must be resolved against a retroactive effect"); *Harris v. Freeman*, 881 P.2d 104, 107 (Okla. Civ. App. 1994) (explaining that statutes altering "the legal character of past transactions" cannot be said to be procedural or remedial and thus may not be applied retroactively).

[43] The Rhode Island False Claims Act provisions on which Relators rely (*i.e.*, R.I. Gen. Laws § 9-1.1-1 *et seq.*) did not become effective until July 1, 2007. Accordingly, the Rhode Island statute may not be applied retroactively to the alleged misconduct at issue in this case occurring before July 1, 2007. *See Pion v. Bess Eaton Donuts Flour Co.*, 637 A.2d 367, 371 (R.I. 1994) ("Generally, it is presumed that statutes and their amendments are 'to operate prospectively unless it appears by clear, strong language or by necessary implication that the Legislature intended to give the statute retroactive effect.'") (quoting *VanMarter v. Royal Indem. Co.*, 556 A.2d 41, 44 (R.I. 1989)).

[44] *See* Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.* The Tennessee FCA became effective July 1, 2001. *See* 2001 Tenn. Pub. Acts Ch. 367. Although the statute purports to allow retroactive application, Relator's claims under this statute should nevertheless be dismissed because applying them to the alleged misconduct at issue in this case before July 1, 2001 would violate the *Ex Post Facto* Clause of the United States Constitution. U.S. Const. art. I, § 10; *see, e.g.*, Ex. 24*, New Mexico ex rel. Foy*, No. D-101CV200801895.

Virginia (Count Sixteen) (effective date January 1, 2003);[45] Wisconsin (Count Twenty-Six) (effective date October 27, 2007).[46]

E. Relator's Claims Are Barred by Statutes of Limitation.

As with the federal FCA, the state statutes upon which Relator relies are generally[47] subject to six-year statutes of limitation that are not conditioned on the discovery or knowledge of false claims but instead operate as absolute bars. Accordingly, eighteen of the twenty-five[48] state counts are barred to the extent they are based on conduct occurring before September 18, 2003 (six years from the date Relator first filed her suit);[49] an additional two of the twenty-five

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[45] *See* Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.1 *et seq.* (effective Jan. 1, 2003); *see also Adams v. Alliant Techsystems, Inc.*, 544 S.E.2d 354, 356 (Va. 2001) (holding that statutes are "always to be construed as operating prospectively, unless a contrary intent is manifest.") (quoting *Duffy v. Hartsock*, 46 S.E.2d 570, 576 (Va. 1948)).

[46] *See* Wisconsin False Claims for Medical Assistance Act, Wis. Stat. Ann. § 20.931(15) (effective October 27, 2007). Although the statute purports to allow retroactive application, Relator's claims under this statute should nevertheless be dismissed because applying them to the alleged misconduct at issue in this case before October 27, 2007 would violate the *Ex Post Facto* Clause of the United States Constitution. U.S. Const. art. I, § 10; *see, e.g.*, Ex. 24 *New Mexico ex rel. Foy*, No. D-101CV200801895.

[47] The New Mexico False Claims Act (Count Twenty) and the Texas Medicaid Fraud Prevention Act (Count Fifteen) are each subject to four-year absolute statutes of limitation.

[48] This excludes Count Twenty-Three for reasons discussed in footnote 22.

[49] Delaware False Claims and Reporting Act, Del. Code. tit. 6, § 1209(a)(1); District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-381.05(a); Florida False Claims Act, Fla. Stat. § 68.089(1); Georgia False Medicaid Claims Act, Ga. Code § 49-4-168.5; Hawaii False Claims Act, Haw. Rev. Stat. § 661-24 (while Relator has alleged that the State was unaware of the false claims, she fails to allege that the State also *should not have known* of those claims); Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. 175/5(b)(1); Indiana False Claims and Whistleblower Protection Act, Ind. Code. § 5-11-5.5-9(b)(1); Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:439.1(B); Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5K(1); Michigan Medicaid False Claim Act, Mich. Comp. Laws § 400.614(1)(a); New Hampshire Medicaid Fraud & False Claims Act, N.H. Rev. Stat. § 167:61-b, VII(a); New Jersey False Claims Act, N.J. Stat. § 2A:32C-11(a); Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.170(1); Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. tit. 63, § 5053.6(B)(1); Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-5(b)(1); Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-184(b)(1); Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.9.

state counts are barred to the extent they are based on conduct occurring before September 18, 2005 (four years from the date Relator first filed her suit).[50]

F. Counts Twenty and Fourteen Should Be Dismissed for Lack of Standing or Lack of Statutory Authorization to Pursue the Claim.

Relator's Count Twenty asserts that Abbott's alleged conduct violated the New Mexico False Claims Act, N.M. Stat. § 27-14-1 *et seq.* (*See generally* Am. Compl. ¶¶ 322-330.) However, under that statute, only "affected persons" may bring private civil actions. N.M. Stat. § 27-14-7(B). The term "affected persons" is not defined under New Mexico law; however, federal courts have unambiguously interpreted it to mean "New Mexico residents." *See Solvay* I, 823 F. Supp. 2d at 520-21, *order vacated in non-relevant part on reconsideration by Solvay* II, 2012 WL 1067228. Relator is a Florida resident. (Am. Compl. ¶ 29.) She therefore lacks standing to assert a claim under the state statute and Count Twenty of the Complaint must be dismissed.

Count Fourteen asserts that Abbott's alleged conduct violated the Tennessee False Claims Act, Tenn. Code § 4-18-101 *et seq.* (*See generally* Am. Compl. ¶¶ 272-280.) However, to the extent Relator also maintains that Abbott's alleged conduct violated the Tennessee *Medicaid* False Claims Act, Tenn. Code. § 71-5-181 *et seq.*—as she does, *see id.* ¶¶ 265-271 (asserting violation of the Tennessee Medicaid False Claims Act)—Count Fourteen must be dismissed because Tennessee law does not permit a private litigant to pursue such a claim. *See* Tenn. Code § 4-18-108 (Tennessee False Claims Act: Applicability) ("This chapter shall not apply to any conduct, activity or claims covered by the Medicaid False Claims Act[].").

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[50] New Mexico Medicaid False Claims Act, N.M. Stat. §§ 27-14-13(A), 37-1-4; Texas Medicaid Fraud Prevention Act, Tex Civ. Prac. and Remedies Code § 16.051; *see United States ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 817-18 (E.D. Tex. 2008).

CONCLUSION

For the foregoing reasons, this Court should dismiss the Complaint in its entirety.

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Respectfully submitted,

By: /s/Marc J. Sonnenfeld

Marc J. Sonnenfeld
John C. Dodds
Dirkje Camille Frey
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5000

Mark Filip*
Henry J. DePippo*
Elizabeth S. Hess*
KIRKLAND & ELLIS LLP
300 N. LaSalle
Chicago, IL 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200

Counsel for Defendant Abbott Laboratories

**admitted pro hac vice*